IMPAC³T

WP2 Scenario definition and process mapping

D 2.3 Report on analysed case studies with GP transfer paths

AUTHOR(S): Lisa Cowey, Laszlo Bacsa, Janne Eskola, Ana De Leon, Ed Maughfling, Girish Somawarpet, Tommi Järvinen, and Natalia Zhuravleva

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List of Acronyms

AHSS	Arts, Humanities and Social Sciences
CC	Creative Commons
COA	Clinical Outcome Assessments
EBQ	Eating Behaviour Questionnaires
EU	European Commission
FOC	Free of Charge
GGC	Guiding Good Choices®
IP	Intellectual Property
MS	Member States
NFP	Non-For Profit
PROs	Public Research Organisations
STEM	(Science, Technology Engineering Maths
TTO	Technology Transfer Offices
YES	Youth Empowerment Solutions

Keywords list

- Intellectual Property
- IPR management
- Licensing
- Tool-box
- Patent
- Classical+ licensing
- Crisis licensing
- Co-creation licensing

Disclaimer

Table of Contents

1. Introduction to the project and deliverable

This document is Deliverable 2.3 of the IMPAC3T-IP project.

IMPAC3T-IP is an ambitious coordination and support action that aims to develop, pilot and support the sustainable adoption of a scenario-based licensing toolbox through a certified user and trainer programme, for efficient IP licensing for market uptake and societal value creation. IMPAC3T-IP explores three main licensing scenarios:

- Classical Plus – licensing that encompasses newer types of IP assets e.g. assets that are not patent based and are therefore different to the assets that have formed the main part of the traditional for-profit licensing approach.
- Crisis – licensing that takes place in response to or to prevent crisis situations such as emerging or preventable medical emergencies.
- Co-creation – licensing that takes place as a result of interactions involving multiple different stakeholders and that goes beyond classical collaborations and contract research.

This document is an output of Work-Package 2: Scenario definition and process mapping.

1.1. Aims and objectives of WP2

Work Package (WP2) had five main tasks:

Task 2.1 Establish special interest groups (3S and 3P)

Three small special interest groups (SIGs) were set up with representatives from public and private licensing communities and policy makers, to support the exploration and analysis of each of the 3 main scenarios outlined above.

Task 2.2 Definition of Scenarios

The three main scenarios were explored through situational analysis, key players, types of IPR, and desired outcome e.g. purpose of the licensing (economic, impact, social, crisis or to realise co-creation) as well as boundary conditions and any clear legal aspects identified.

Task 2.3 Mapping of processes and intervention points

Each defined scenario was mapped though a series of analysed examples to identify 'intervention points' where the application of a tool could facilitate progress towards the desired outcome.

Task 2.4 Study of drivers

Work was undertaken to understand the drivers for enterprises in engaging in licensing beyond pure economic gain.

Task 2.5 Collection of Case studies

Case studies were identified and analysed to further illustrate the different scenarios and to capture the best practice aspects that make the example transferable for others.

1.2. Outcomes

This document presents the results of Task 2.5 namely the extended Case Studies with analysed Good Practice transfer paths for those seeking to adopt them. For a detailed introduction to the three scenarios and the methodology used please see deliverable D2.1.

2. Case Studies

2.1. Classical Plus Case studies

Health and medical questionnaires

Research work related to the health and behaviour of both humans and animals frequently involves the use of surveys and questionnaires. Classically, the output has been a research paper drawing conclusions based on the statistically analysed data with the questionnaires appended as an Annex to the paper. However, once answers can be interpreted, the questionnaires become a valuable resource for others to use. Several case studies are detailed below.

2.1.1. Canine Behaviour Calculator

Background

The Online Canine Behaviour Calculators are a series of unique, clinically validated scales designed to assess various behavioural traits in dogs, created by Professor Daniel Mills of the Animal Behaviour, Cognition & Welfare Group at the University of Lincoln.

IP Developed

Copyright in a range of six Canine Behaviour Calculators (questionnaires) and associated documents on how to use, score and interpret the results.

Access Models

The canine behaviour calculators were made available via the University of Lincoln's e-lucid storefront in order to facilitate the dissemination of these questionnaires to as many end users as possible. End users / licensees ranged from individual dog owners to vet practices of varying sizes in over 60 countries.

This particular access model was chosen firstly because hosting on University servers was viewed as a potential IT security risk and secondly because the publication of clinical tools in journals had previously been an issue due to disputes over copyright ownership.

Each of the tools is available under a non-exclusive, perpetual licence for non-commercial research or educational use. All licence requests are automatically approved by the platform. Where a commercial licence is required, organisations are requested to apply via email.

Outcomes and Results / Project Sustainability

Simplified access to these tools has enabled thousands of dog owners and community vets to assess, monitor and manage problems relating to anxiety, sound sensitivity and impulsivity resulting in considerable societal benefit.

As well as licence numbers providing a quantitative measure of impact the licensor has included a specific clause that the licensee will agree to provide information relating to their use of the tools.

Whilst all licences transacted via the platform are currently free of charge, the sustainability of the research is maintained in part by the consultancy services offered through the Animal Behaviour Clinic, at the University of Lincoln's City Centre campus.

Status of Research

Research into canine behaviour is ongoing and a new behavioural assessment tool was added to the portfolio in early 2024.

Lessons learned

An online platform can effectively expedite the dissemination of IP assets to a large number of users, including the general public, and reduces the considerable administrative burden of managing the process.

User feedback is a very effective way of assessing the impact of research outputs but is rarely considered when drafting licence Terms & Conditions. Including appropriate wording, e.g. that the licensee will agree to provide information relating to their use of the tools, is a useful way to facilitate the collection of qualitative information – e.g. for REF cases.

An easy to manage process / platform to control access to copyright assets, that previously would have been published in scientific / academic journals, avoids disputes over rights ownership.

Sustainability of the research project / group producing IP assets doesn't always need to be maintained by licence revenues - in this instance the group offers consultancy services.

For more information visit:

https://ipstore.lincoln.ac.uk/product/online-canine-behaviour-calculators

https://staff.lincoln.ac.uk/dmills /

dmills@lincoln.ac.uk

https://animalbehaviourclinic.lincoln.ac.uk/

2.1.2. Eating Behaviour Questionnaires (EBQ)

Background

The Eating Behaviour Questionnaires (EBQs) are a well-established set of 11 clinically validated tools, available in English and a number of other languages including French, Spanish, Polish, Bulgarian, Greek and Turkish. They were developed by a team led by the late Professor Jane Wardle and Professor Claire Llewellyn and can be used in research or clinical trials relating to diet, obesity / excess weight gain or eating disorders.

The team wanted to control access from a single secure website to ensure the integrity of the questionnaires, whilst not presenting a barrier to genuine users to help deliver maximum patient impact.

The team also needed support for rights clearance and to manage copyright protection and ownership of translations.

IP Developed

The associated intellectual property consists of copyright material in a set of clinically validated self-report psychometric tools (in English and other languages) and scoring guides.

Access Models

The XIP licensing website, managed by UCLB Ltd (the technology transfer office and commercialisation company of University College London), provided a single point of access for all the questionnaire materials (including translations and scoring systems). These can be licensed free of charge by non-commercial organisations for research use.

For other uses, including commercial use, prospective licensees can currently submit an online query. And, once a revenue share agreement (between UCL and a grant funding body) has been signed, commercial licences will also be configured on XIP.

The non-commercial licence T&Cs (terms and conditions) were drawn up by UCLB and permits use of the copyright material for non-commercial academic research only. To further ensure the correct usage of the materials, the terms explicitly exclude the development of new products for commercial distribution or any commercial exploitation.

To protect the integrity of the questionnaires, any derivative works (modifications, translations or cultural adaptations) vest in UCLB. UCLB will only offer non-commercial licences for these.

Based on the licencee's specific requirements, UCLB may contract a translation or cultural adaptation of a questionnaire at the appropriate validation level as required by regulatory bodies. UCLB will retain ownership of the translation to be able to licence it to other commercial entities.

Outcomes and Results

Publication on the XIP storefront is very recent (July 2024) but there have already been over 20 licences concluded.

Updating and improvements

No further updates or improvements to the questionnaires are anticipated but where translations are made (either by UCL or by 3rd parties), these will be added to the available portfolio of materials.

Status of Research

The research projects that developed the Eating Behaviour Questionnaires are no longer active. However, Dr Llewellyn has oversight of licensing and any derivative works.

Lessons learned

A single controlled point of access limits misuse of copyright but barriers to access for genuine users must be low for this approach to function well.

Also, of importance when drafting licence terms is to consider not only the copyright of existing materials but also of derivative works, including (especially for clinical questionnaires) translations.

T&Cs of grant funding may allow free of charge licensing of research outputs but any commercialisation may need revenue share agreement before progressing.

For more information visit:

https://xip.uclb.com/products/healthcare-tools/list

a.gatta@uclb.com

/ https://www.ucl.ac.uk/epidemiology-health-care/people/llewellyn

Training and educational resources

2.1.3. 24h QuAAlity: E-learning modules for home-carers

Background to the initiative

Home-carers are not full health care professionals but a key part of the care community. They work in other people's homes, not in a hospital to care for people in the community. Most of these individuals are on short term contracts rather than being full time employees of a healthcare authority. Many of them have come from abroad so there is an added complexity over language. This target group would benefit from E-learning, including by being able to do it flexibly (between shifts) and at their own (2nd language) pace. They are unlikely to be willing to pay for it themselves due to their low hourly pay rates. There may be value for a healthcare authority, or a private agency, of offering E-learning it free / at cost to their contracted workers.

Aims and objectives

The aim of the 24h QuAALity project was to develop and evaluate a distributed client-server software solution for quality assurance of 24-hour care. The application software for personal carers contains an information and training portal for recurring care and nursing situations in German, Slovakian, Hungarian and Romanian, electronic care documentation to support quality assurance and transparency, and integrated emergency management to enable professional responses to emergencies. This should give personal carers security in care situations and help to improve the overall quality of care.

Results

The main result was a distributed client-server software solution for the quality assurance of 24h day-long assistance. The application software for assistants is comprised of a) an information and training portal on recurrent care and nursing situations in German, Slovak, Hungarian and Romanian, b) an electronic care documentation to support quality assurance and c) an integrated emergency management to respond professionally to emergency situations. This should give the caregivers safety in the care situations and help to increase the overall quality of care.

Intellectual Property

The main form of IP in the exploitable results was copyright. This was complex in terms of the multi-media nature of the resources e.g. distributed over different part of the asset (e.g. script, images, software....) and also ownership of the different parts as it was created by multiple authors. There was also a lot of commercially valuable know-how in terms of the content. Finally, there were domain and design rights in the platform. There were complexities in ownership of the different assets because they had been created by a consortium of organisations.

Outcomes

In 2021, IPR owned by the partners was transferred to a company who will now take the exploitation forward under a licensing agreement with the consortium partners. The learning models will be made available at certain price.

Lessons learned

Joint creation and multiple claims to ownership of IP rights proved to be a barrier to early commercialisation. This was resolved through clear assignment of rights and a joint license agreement between all partners and the company designated to exploit the IPR. However, auditing ideally needs to take place regularly during development to identify IP and also possible claim to authorship/ownership; final transfer of rights and clear freedom to operate is then facilitated.

The T&C of the license between the project partners and the exploiting company took some time to negotiate. The final transfer included conditions for:

- upfront payment and possible bonus payment.
- revenue share until a certain threshold is reached after which unrestricted exploitation right for the educational videos is transferred to the exploitation company.
- fundamental revisions to the content of the E-learning courses, (any case when a learning video has to be newly created), when the university will receive a payment per course.
- University to retain all rights of use of its research results for the purpose of research and teaching. It is further clarified that the university will continue to fulfil its publication obligation according to item 14 of the consortium agreement

For more information visit:

- https://projekte.ffg.at/projekt/3076586
- https://www.fh-campuswien.ac.at/en/departments/nursing-science/booster-for-a-young-science.html

2.1.4. REACT (REducing bACTerial infections) Materials

Background

Health and social care professionals (e.g. care workers, nurses delivering healthcare for the homeless, community pharmacists, hostel workers) that come in contact with people who inject drugs may lack the confidence to discuss the risk of skin infections, which have the potential to cause serious health complications.

To tackle this problem, Dr Harriet Fisher & Dr Jo Kesten (National Institute for Health & Care Research (NIHR) Health Protection Research Unit in Behavioural Science and Evaluation at The University of Bristol) developed a toolkit for service providers to support discussions with people who inject drugs about caring for their veins and making changes to help prevent bacterial infections. The toolkit consists of a set of information cards as well as an introduction / instruction manual.

The team hoped to make the materials available for the long term, with minimal barriers to access and to collect feedback from users.

IP Developed

The intellectual property consists of the REACT toolkit and introduction / instruction manual (copyright).

Access Models

In a previous similar project, the research team found distributing information materials via a commercial partner (a syringe manufacturer) was a barrier to access and dissemination for some people. So, the aim was to find a sustainable way to support free of charge dissemination of the REACT toolkit and to be able to gather evidence of the impact.

The materials were licensed, non-exclusively and free of charge, via the University's Express Licensing portal. The permitted use covered supporting people who inject drugs to care for their veins and make changes to help prevent bacterial infections and associated health complications.

The license included two notable clauses that support the impact of these materials:

Firstly, the licensee is required to acknowledge use of the REACT Materials in publications by citing the original journal publication. Secondly, the team requests permission to seek licensee feedback – this is managed via an 'opt-in / opt-out' question configured into the online licensing process.

Outcomes and Results / Project Sustainability

Since publication of the materials on the Express Licensing portal in March 2023 the material has been licensed nearly 200 times. In addition to this quantitative measure of impact, the team sent a follow-up survey to users who opted in to providing feedback on their use of the materials. The response rate was relatively low (12%) however the results provided insights into the best ways to further disseminate the materials, e.g. by social media and through workplace newsletters. It also demonstrated that the materials had been used to support discussions with people who inject drugs.

The survey, and feedback provided via the contact function on the licensing portal, also highlighted that some staff working in NHS (National Health Service) trusts had issues downloading digital files (firewall issue).

Status of Research

The outcomes of the dissemination project have been submitted for presentation at the UK Health Security Agency (UKHSA) Scientific Conference. Further dissemination activities, utilising insights gained from the user survey, may follow this presentation in 2025.

Lessons learned

Even for simple, free of charge, dissemination of a written toolkit the partner needs to be the right one. Being partnered or sponsored by a commercial organisation to keep the project sustainable may not always work. The partner may not have the right visibility of the target audience and/or may even act as a barrier to adoption.

Increased impact from IP assets can come from capitalising on a licensing network and mandating that users cite the research. Being able to collect feedback from users is also beneficial for assessing impact.

Where digital assets are likely to be licensed by organisations with strict firewall policies (NHS trusts, government departments, etc), download of licensed assets may be problematic whatever the platform. This may need to be factored into the distribution methods.

For more information visit:

https://express-licences.bristol.ac.uk/product/react-reducing-bacterial-infections-materials or contact Clare Thomas clare.thomas@bristol.ac.uk from the Health Protection Research Unit in Behavioural Science and Evaluation, University of Bristol.

2.1.5. Guiding Good Choices® (USA)

Background

Guiding Good Choices® (GGC) is a family skills-training program developed to promote healthy development and reduce risky behaviours, such as drug use, among teenagers. The original version, titled "Preparing for Drug-Free Years," was created by J. David Hawkins and Richard F. Catalano and gifted to the University of Washington's (UW) Center for Communities That Care (CTC).

The primary motivation behind developing GGC was to enhance positive parent-child interactions and equip parents with tools to prevent their children's drug use and related behavioural problems. As a part of UW's broader mission to contribute to public health, the program focuses on providing preventative education to communities.

IP Developed

The intellectual property for GGC includes a comprehensive education set with course materials in PowerPoint format, videos, guides, evaluation tools, and a registered trademark for the program's name. Additionally, there is an optional printed GGC Workshop Leader Guide, available in both English and Spanish.

Access Models

The goal of the access model for GGC was to ensure sustainable distribution and accessibility of the program to agencies that serve the target audience—parents and caregivers of middle-school-aged children in grades four through seven. UW's Tech Transfer Office, CoMotion, facilitated the licensing process, by using e-lucid's delivery platform, making GGC available via a 'click-through' license execution model that includes necessary approvals, such as export control review and payment.

The rationale for this approach was rooted in the need for a pragmatic and sustainable distribution mechanism that would generate revenue to fund ongoing product improvements. Market research and reviews of similar evidence-based prevention programs guided the development of a membership-based business model. The options offered were a 1-year membership subscription for $240 per user or a 3-year membership subscription for $500 per user, with an additional cost for the printed guide. This approach aligned with UW's goals of public service and maintaining an inclusive access model, avoiding more exclusive or prohibitively expensive distribution strategies.

Outcomes and Results

In the three years since the program's publication in April 2021 on the e-lucid-based CoMotion store, GGC has been licensed over 400 times. The revenue generated has been reinvested in product development and maintenance, supporting a sustainable model that continues to evolve based on feedback and new research findings.

GGC's impact extends beyond economic benefits; it has been validated through two randomised controlled trials that demonstrated positive, lasting effects on the well-being of participating teenagers and their families. Four to six years after initial participation, youths were 41% less likely to use alcohol and marijuana, 54% less likely to progress to more serious substance abuse, and 28% more likely to remain drug-free compared to controls.

Status of Research Work / Ongoing Work

GGC is a continually evolving program. The University of Washington has implemented a community of practice with monthly sessions and offers technical assistance to support the adoption and use of the program. As needs and feedback from the community emerge, the program undergoes updates and enhancements to remain relevant and effective in its preventive mission.

Lessons Learned

- **Navigating Internal Processes:** Drafting the initial license with academic teams was challenging due to the need for education and lengthy approval times. Using a checklist of critical points and standardised, non-negotiable clauses helped streamline the process.
- **Sustainable Business Model:** Establishing a sustainable business model that balanced affordability for target users with financial viability for the university was crucial. The subscription-based model proved effective in generating revenue that supports ongoing improvements.
- **Support Mechanisms:** Establishing a community of practice and technical support played a crucial role in promoting the adoption and sustained use of GGC.

For more information, visit:

About Guiding Good Choices

Guiding Good Choices materials

Or contact UW CoMotion Licensing at license@uw.edu

2.1.6. YES: Youth Empowerment Solutions (USA)

Background

The Youth Empowerment Solutions (YES) program is led by Marc Zimmerman at the University of Michigan School of Public Health in collaboration with community partners, including Flint's Youth Violence Prevention Center. The program was created around 2010 to address the pressing issue of youth violence in communities across the United States.

The YES program empowers youth to take active roles in their communities, working alongside adults to foster positive changes and reduce violence. This youth-centred approach was driven by the recognition that traditional top-down methods often fail to engage the youth they aim to support. The program leverages a collaborative model where youth lead initiatives with the guidance of adult partners, aiming to create sustainable community impact and enhance the quality of life in underserved areas.

IP Developed

The YES program includes several copyrighted materials that form the core of its intellectual property:

- **Youth Empowerment Solutions Curriculum:** Available in both Multicultural and African American versions.
- **Implementation Guide:** A detailed guide for community partners to implement the YES program effectively.
- **Evaluation Materials:** Tools and resources for assessing the impact and effectiveness of the program.
- **Supporting Materials:** Includes brochures, videos, research publications, music, and multimedia content designed to enhance the learning experience and engagement.

These resources collectively aim to equip youth and adults with the knowledge and tools to implement and sustain community change efforts effectively.

Access Model

The YES materials have moved across different delivery platforms since its initial distribution. They are now made freely available through the e-lucid platform, a centralised distribution point where users can register, agree to the terms and download the resources. This approach allows the YES team to track engagement and provide follow-up support, including updates on new materials, training and grants opportunities, and events.

The YES program's access model maximizes impact by offering resources freely to communities in need, empowering youth and organizations without financial barriers. This inclusive approach aligns with the University of Michigan's mission of public service and social impact, ensuring that the program's benefits reach as many communities as possible by avoiding paid or exclusive distribution models that could restrict participation, especially in underserved areas.

Project Sustainability

The YES program is sustained through funding from federal agencies (such as NIH-HHS and CDC), private foundations (like The John Mohme Foundation), and internal funds from the University of Michigan. This diverse funding base supports the ongoing distribution and evolution of the program without needing to charge for access.

Outcomes and Results

The YES program has distributed over 2,000 orders of its resources in the last five years, establishing a significant outreach and connection with communities nationwide. Studies highlight YES's success in empowering youth, reducing violence, and fostering community change can be found here.

Status of Research

The YES program is an ongoing initiative that continues to evolve based on community feedback and research findings. Updates include adding multicultural versions of the curriculum, and new modules focused on specific themes, such as healthy relationships. This ongoing refinement ensures that the program remains relevant and effective in meeting its goals.

Lessons Learned

- **Distribution Mechanism**: A simple, user-friendly platform is crucial for reaching the target audience.
- **Sustainability:** Free access, supported by diverse funding, has been vital to growing the project.
- **Follow-up and Outreach:** Ongoing community engagement and feedback have allowed the project to evolve. Enhancing tools facilitating this interaction will be essential for sustaining connections and support.

For more information, visit:
About YES Program

YES Implementation Guide

2.1.7. Meals on Wheels infographics (UK)

Background

As part of their social care provision, around 30% of local authorities in the UK provide 'Meals on Wheels' (a service that takes hot meals to the homes of adults with care and support needs, either for free or for a small payment) directly or via outsourcing to charities and private contractors.

In a research study led by Dr. Angeliki Papadaki, from the School for Policy Studies at the University of Bristol, Meals on Wheels stakeholders (managers, drivers and service users) were interviewed to understand what works well in Meals on Wheels and to learn about the challenges of the service. One of the results of this research was a set of infographics, developed in conjunction with people with 'lived experience' of the service (i.e. the users and providers of Meals on Wheels). The infographics are aimed at GPs, hospital-based clinicians, and social and community carers and workers to inform referral decisions to Meals on Wheels services.

The infographics can also be used by Meals on Wheels providers as a resource to raise awareness of their services on their websites and publicity materials and by commissioners and policy makers as a resource to inform decisions about reintroducing Meals on Wheels services.

The aim was to disseminate the materials as widely as possible, to support increasing awareness of and create publicity for Meals on Wheels. A further driver was the collection of stakeholder feedback from users of the resource.

IP Developed

The intellectual property consists of the infographics (copyright).

Access Models

The resources have been made available via The University of Bristol's e-lucid storefront, free of charge for non-commercial use.

Non-exclusive copyright licence for raising awareness of Meals on Wheels services, supporting referral decisions, informing decisions about funding, continuation and / or enhancement of services, and/or educational or research purposes.

The license also included the following specific wording to explicitly exclude certain uses:

"shall not sub-license, distribute, adapt, modify, translate transfer, sell, exploit or use the Meals on Wheels resource in any way or for any other purpose whatsoever."

Outcomes and Results / Project Sustainability

The resources have been licensed over 30 times in the last 12 months but the PI had been hoping for a larger impact, partly because she had widely shared the product url via email to over 600 people.

Status of Research

This research is ongoing and currently Dr. Angeliki Papadaki is developing an interactive map of Meals on Wheels providers in the UK, which can also be used to raise awareness of services.

Lessons learned

The infographics were developed in conjunction with people with 'lived experience' i.e. the users and providers of Meals on Wheels. The University Research Ethics Committee and Technology Transfer Office were able to advise the research team on the need to obtain consent forms including for use of copyright. This was deemed not necessary for the infographics but it was sought for people with lived experience who participated in the associated film production.

For more information visit:

https://research-information.bris.ac.uk/en/persons/angeliki-papadaki

or contact Dr. Angeliki Papadaki, School for Policy Studies, The University of Bristol

Angeliki.Papadaki@bristol.ac.uk

2.1.8. KiVa: A Finnish anti-bullying program (FL)

Originator: University of Turku, Finland

Background to and objectives of the initiative

KiVa is an anti-bullying program targeted to schools providing comprehensive education for children aged between 6 and 16 years old. The goals of the KiVa program are to prevent bullying from happening via effective methodology in order to minimize the negative effects of bullying. It includes three components: prevention, intervention and monitoring. The University of Turku was contracted by the Finnish Ministry of Education and Culture in 2006 after two important amendments to the legislation, including the requirement to provide a safe learning environment (1999) and the obligation to provide a written plan for the prevention of bullying (2003) had failed to decrease bullying according to the National school health promotion study conducted by the National Institute of Health and Welfare each year.

The program was developed and trialled over three years by the University of Turku, Finland with funding from the Finnish Ministry of Education and Culture. The program was based on a strong research effort and its effectiveness tested and proven in a national trial involving a group of schools using KiVa program who were compared to a non-KiVa control group. This meant that the proposed interventions were evidence-based and the effectiveness of KiVa had been proven scientifically. Since 2009, KiVa is available for all schools in Finland.

Results

KiVa Antibullying Program offers a wide range of materials for schools adapted to the children's age.

KiVa proprietary material is targeted to the school community, including parents, and includes:

- Teachers' manuals
- Presentation graphics
- Video clips
- Online games
- Forms to be used in separate discussions with the bullied student and the child who has bullied
- Online surveys for students and staff
- Parents' guide
- Info letters for parents
- Vests, posters
- Instructions and support on how to implement the program efficiently

Outcomes and impact

In Finland, the KiVa program has been evaluated in a large randomized controlled trial including 117 intervention schools and 117 control schools.

- The program has been shown to reduce both self- and peer-reported bullying and victimization significantly.
- It influences multiple form of victimization, including verbal, relational, physical, and cyberbullying.

- In addition, positive effects on school liking, academic motivation and achievement have been reported.
- KiVa also reduces anxiety and depression and has a positive impact on students' perception of their peer climate.
- A remarkable 98% of victims involved in discussions with the schools' KiVa teams felt that their situation improved.
- Finally, Finnish data from more than 1,000 schools that started the implementation of KiVa in fall 2009 showed that after the first year of implementation, both victimization and bullying had reduced significantly.

KiVa program has been and is still evaluated in several countries: the first international studies from the Netherlands, Estonia, Italy, and Wales show that KiVa program is effective outside of Finland as well.

KiVa Antibullying Program is part of the wider Education Finland initiative a governmental cluster program supporting the best education providers in their growth on the international market. The total revenues generated by Finnish education export were 387 million in 2019, 498 million in 2020, and 646 million in 2021.

Lessons Learned

- To develop a program that would be accepted for national use it was important to test and verify its effectiveness through evidenced based and so to undertake rigorous scientific research and testing.
- Significant funding was needed to undertake the original research and the government commissioned the study used to develop also the training materials for supporting the Schools and Partners.
- It was clear from the beginning that funding would be needed by schools to be able to adopt and run the program and this was also made available by the government in the early years.
- Funding was needed to be able to continue to make the program available nationally through education export to generate revenue was an early part of the underlying business model.
- Creating a high quality trusted 'brand' for the program was important and selecting partners abroad who share values and can make a long-term commitment to the program is a strong focus for the KiVa team.
- KiVa licensed partners with just one organization in each country wishing to adopt the program to avoid compromising quality by multiple partners competing for a national market.
- There is a need for strong human resource support to create and maintain the different long-term partnerships that are formalized through a commercial contract.

Access Model

The KiVa materials are covered by copyright and trademark protection and the University of Turku has exclusive rights to exploit all KiVa materials.

Derivative versions e.g. translations, are also owned by the University of Turku. These are produced in collaboration with the KiVa licensed partner for that specific country to which the material is translated to enable proof reading of a professional translation and some localization of the legal aspects.

No significant new materials have been produced since the original funded research project finished. However, some updates have been possible e.g. to reflect cyber-bullying and sexual harassment. Where complementary new materials are developed by a partner, e.g. to enable better local delivery, there is the option for these to be covered by the KiVa trademark. However, this is assessed on a case by case basis.

KiVa program is licensed to Finnish Schools and to Licensed partners abroad under a commercial **licensing agreement**. This sets out the price of access and support as well as the scope of the partnership.

International delivery was always anticipated as a way to generate revenue to secure sustainability of the national program. Materials are currently available in 16 languages. KiVa program forms a long-term partnership with just one organisation in each country. This model ensures that multiple partners do not compete to deliver at a national level and possibly compromise the quality of the implementation. Unlike the situation in Finland where The University of Turku works with individual schools directly, when operating internationally The University works with the designated Licensed partners, who then takes responsibility for cascading the program to schools.

Around 90% of international inquires come from 'word of mouth' recommendations and the KiVa team at the University of Turku will carefully investigate a possible collaboration before concluding an agreement. It is important that values are well aligned and that the local partner can provide the security of a long term business plan for delivery and support to schools and provide confidence that the KiVa reputation will be safeguarded.

All prices are agreed upon through the licensing agreement. It is possible to commit to a single payment which covers all the costs for the duration of the agreed partnership, or a yearly basic fee and royalties. In both models the contract is signed for 3-5 years at a time and is renewable. The costs include the right to use the KiVa trademark, distribute KiVa program in the agreed region, KiVa materials including the monitoring tool, as well as setting up of the infrastructure for the implementation of KiVa.

The KiVa material also includes the monitoring tool that enables each KiVa school to monitor the use of the program and their school wellbeing.

For more information visit: https://www.kivaprogram.net/

2.1.9. Teaching English Grammar: Englicious

Background

When grammar was reintroduced to the National Curriculum for England in 2014 after a 50 year hiatus, teachers found they had no adequate tools or training to support their teaching.

The team from University College London (UCL) led by Bas Aarts and Sean Wallis secured initial funding from The Arts and Humanities Research Council (AHRC) to support the creation of a website (www.englicious.org) and the printed materials (English Grammar Knowledge Organisers, Laminated Grammar Wall Posters and Double-sided Grammar Flashcards).

IP Developed

The intellectual property consists of the website and printed resources (copyright).

Access Models

The aim of the team was to create maximum impact by having the resources accessible to as many people as possible.

A 'Freemium' model was adopted whereby some resources (Videos, Games, a Glossary) were made available via the free subscription website whilst the printed materials were sold via UCLB's e-lucid storefront 'XIP'. The prices for these resources range from £4.95 to £79.99.

Outcomes and Results / Project Sustainability

The free website has approximately 15,000 users (teachers) subscribers.

The printed materials have been licensed over 400 times with revenues of c£10,000 since they were published on the XIP licensing website (managed by UCL Business (UCLB) the technology transfer office of UCL) since 2017.

The website also offers paid CPD courses and the combination of these revenue streams has to date help to support the maintenance of the website and resources.

The project was the subject of a REF2021 (Research Excellence Framework) case study and helped the department to achieve a 4* rating (the highest possible) which indicates research quality that is world-leading in terms of originality, significance and rigour and helped to allocate funding.

The long term plan is to find a commercial partner to help market and deliver these resources to ensure long-term sustainability.

Status of Research

The research that underpins these resources is largely finished but there is some development work on the resources to complete.

Lessons learned

The access / commercialisation models for IP assets from the Arts, Humanities and Social Sciences (AHSS or sometimes referred to as SSHA) vary considerably to those from STEM research and until recently TTOs had very little experience. This will remain a challenge, particularly to those smaller offices.

A hybrid / freemium model, whereby some resources can be made available, free of charge, from one source (in this case a subscription website) whilst other materials can be licensed for a fee from another (UCLB's XIP website) are not incompatible with each other and can be considered.

Finally, for access models to be sustainable they can (or even should) change over to time to adapt to circumstances (e.g. the stage of the research project, the success of initial access models, time

commitment of the academic team). What worked in the early stages of dissemination may not be the best way to managing licensing / deliver impact long-term.

For more information visit:

http://www.englicious.org/

https://xip.uclb.com/products/publications/English-Grammar/list

Data Bases, Data Sets and Digital Libraries

2.1.10. FinnGen: Genome and health data from a Finnish biobank

Originator: The Institute for Molecular Medicine Finland (FIMM) and Helsinki Biobank, with coordination by the University of Helsinki.

Background and Objectives of the Initiative

FinnGen was launched to leverage Finland's unique position in biomedical research, biobanking, and digital healthcare data. Finland's Biobank Act (2013) and the Act on the Secondary Use of Health and Social Data (2019) created the infrastructure for large-scale data collection and research. These legislative frameworks allow the broader use of genomic and healthcare data, fostering breakthroughs in personalized medicine and health innovations.

The primary objectives of FinnGen are:

1. To produce medical innovations by leveraging the combination of health registry and genome data.
2. To boost Finland's position as a pioneer in biomedicine and personalized healthcare.
3. To create a cooperation model between the public sector and healthcare industry.
4. To provide early access to new personalized treatments and health innovations for all Finns.

The initiative aims to involve the Finnish population, with over 500,000 participants, to better understand the genetic basis of diseases and provide data that could lead to the development of new treatments. It also seeks to foster collaboration between public institutions and the pharmaceutical industry to make Finland a leader in biomedical research and innovation.

Highlights:

- Scientific breakthroughs: New therapeutic targets for common and rare diseases identified through data integration and analysis.
- Public-private collaboration: Strong partnerships between universities, public biobanks, and international pharmaceutical companies.
- Global positioning: Finland's position as a leader in biomedicine and genomic research has been strengthened.
- Personalized healthcare: Accelerating the development of personalized treatments for patients.
- Future benefits: Genome data will support disease prevention, diagnostics, and the development of personalized medicine in the future.

Partners

The FinnGen project involves universities, hospitals, biobanks, and pharmaceutical companies. More than 40 people are working on the project, most of them at the University of Helsinki. Coordinating organizations include:

- University of Helsinki (FIMM) – Coordinator of the FinnGen study.
- Helsinki Biobank – Coordinator of sample collection.

- THL – Coordinator of register data.

Biobank partners include Auria Biobank, Northern Finland Biobank Borealis, Arctic Biobank, Central Finland Biobank, Finnish Clinical Biobank Tampere, Biobank of Eastern Finland, Helsinki Biobank, THL Biobank, FRC Blood Service Biobank, and FHRB Biobank.

Funding

FinnGen has attracted over €144 million in funding, with approximately €20 million from Business Finland and the remainder from 13 international pharmaceutical partners, including AbbVie, AstraZeneca, Biogen, Boehringer Ingelheim, Celgene/Bristol-Myers Squibb, Genentech (a Roche Group member), GSK, Janssen, Maze Therapeutics, MSD/Merck, Novartis, Pfizer, and Sanofi.

Data Management

Biobank samples and health data are core to the FinnGen initiative. Data from Finnish national health registers and biobank samples can be accessed for research purposes, benefiting pharmaceutical companies and academic institutions.

Data management in FinnGen ensures that data access and privacy are handled securely and ethically, complying with Finnish laws (e.g., the Biobank Law, the Act on the Secondary Use of Health and Social Data) and the EU General Data Protection Regulation (GDPR). Data is released twice a year and made available through portals such as Fingenious® for secure use by researchers. The Risteys tool allows browsing of the data at the phenotype level.

Access fees and conditions.

As shown by Table 1 below It is common for biobanks to charge a fee to cover the service costs for providing access to data.

The Finnish system is based on statutory law: the Biobank Act[3]. This governs issues such as consent and data protection. The act does not differentiate between academic and commercial; anyone can apply and get samples and related data from a biobank. Access requires a positive decision from the biobank (negative decision can be appealed in administrative courts) plus a material transfer agreement. Biobank fees vary based on the nature and volume of the requested samples and data.

As shown by the table below, approaches vary. In contrast to FinnGenn, the Hartwig Medical Foundation takes a fee when accessing data for commercial purposes. Apart from research proposals and access fees, some biobanks and research projects have conditional data access. For example, LifeGene (Sweden), the Danish National Biobank and Hunt (Norway) require applying organisations to be associated with national research institutes or universities. Some organisations directly deny data access from most external parties by involving exclusively their core research partners or data service providers. The 100,000 Genomes Project allows full data access for partner researchers and institutions, while offering a limited data access to commercial parties through a ‘discovery forum’.

Table 1 Access conditions for some health or genomics data bases

Project	**Data Access**			
	Open	Restricted	**Access fee**	Links to data
The Estonian Genome Center		X	**X**	
UK Biobank		X	**X**	
Canadian Open Genetics Repository (COGR)	X			
Hartwig medical foundation (NL)		**X**	**X**	
European Genome Phenome Archive (EGA)		X		
International Cancer Genome Consortium (ICGC)	X	X		
The National cancer Institute (NCI)	X	X		X
Genomic Data Commons (GDC) (USA)	X	X		
European Bioinformatics Institute (EMBL-EBI)	X	X		X
PrecisionFDA (USA)		X		
AHA Precision Medicine Platform (USA)		X	**X**	
The National Genomics Infrastructure (NGI) (SWE)				X
ELIXIR (Europe)				
The 100 000 Genomes Project (Genomics England)		X		
FinnGen (FIN)		X		
LifeGene (SWE)		X	**X**	
The Personal Genome Project (International)			**X**	
Global Alliance for Genomics and Health (GA4GH)				X

2.1.11. Marine Regions data-base

Originator: Flanders Marine Institute/ Vlaams Instituut voor de Zee (VLIZ)

Background to the case study.

Geographic Information Systems (GIS) have become indispensable tools in managing and displaying marine data and information e.g. legal boundaries to territories as well as information on geophysical features such as sandbanks, seamounts, ridges, bays. This information is critical to those operating boats and other ocean going vessels to ensure that they operate safely and in conformance with national and international laws. It is also needed by those developing associated navigational software and associated services.

However, a unique georeferenced standard of marine place names and areas was not available; this hampered several marine geographic applications, for example the linking of these locations to databases to integrate data.

Aims and objectives

The aim of creating the Marine Regions database was to create a standard, relational list of geographic names, coupled with information and maps of the geographic location of these features. This was intended to improve access and clarity of the different geographic, marine names such as seas, sandbanks, ridges and bays and display univocally the boundaries of marine biogeographic or managerial marine areas.

Creators

The 'Marine Regions' database was developed by researchers from the Flanders Marine Institute/ Vlaams Instituut voor de Zee (VLIZ).

Results

The 'Marine Regions' online resource is an integration of the VLIMAR Gazetteer and the VLIZ Maritime Boundaries Geodatabase. The VLIMAR Gazetteer is a database with geographic, mainly marine names such as seas, sandbanks, seamounts, ridges, bays or even standard sampling stations used in marine research. The geographic cover of the VLIMAR gazetteer is global but initially focused on the Belgian Continental Shelf and the Scheldt Estuary and the Southern Bight of the North Sea.

Gradually more regional and global geographic information have been added to VLIMAR and combining this information with the Maritime Boundaries database, representing the Exclusive Economic Zones (EEZ) of the world, led to the creation of marineregions.org.

Funding and sustainability

Marine Regions is managed by the Flanders Marine Institute. Funding for the creation of the VLIMAR gazetteer was provided initially through the EU Network of Excellence MarBEF, but also other European initiatives such as Lifewatch provide the necessary funding for the maintenance and management of Marine Regions. The database depends on ongoing data and knowledge sharing from global, European, regional and national data providers and relevant experts. This is done using Collaboration Agreements. By using collaboration agreements, data providers benefit from belonging to the Marine Regions partnership through increased visibility, access to a variety of data analysis services which benefit from integration of several distributed spatial datasets and gain benefit from the creation of stable unique identifiers.

Access Model

Marine Regions' products were originally licensed under a CC BY-NC-SA (Attribution-NonCommercial-ShareAlike) license[1]. This does not permit commercial use.

The Flanders Marine Institute was approached by commercial companies wanting to be able to legally use the data base inside their commercial products e.g. interpretation of GPS positioning on boats. They requested that the marine regions' maritime boundaries be made available under a CC BY license or under a fully commercial agreement linked to an associated pricing model.

The requests to offer fully commercial licenses created a number of difficulties for the Institute:

1. Internal culture and commercial activity: Some researchers at the institute are unwilling that the database be licensed under commercial terms. They feel it does not fit to the Mission and culture of the Institute which promotes open and FAIR data. Additionally, the developments and work of Marine Regions has been state funded either by project funding or direct institutional funding.
2. Information asymmetry and pricing: A pricing model has not been easy to construct as there are significant asymmetries in information between the institute and the commercials users regarding the 'value' of the data.
3. Commercial licensing agreement clauses: Commercial licensing templates would need to include commercial clauses e.g. disclaimers and waivers to protect the Institute. This would require licensing and legal experience which was not readily available.

Outcomes

From 2019 and version 11 the Institute took the decision to offer the database under a CC BY license[2]. This means that it can be used for commercial purposes but the Institute does not have to negotiate the terms of each individual license. At the moment, the database continues to be licensed under CC BY and commercial use is permitted. In a disclaimer the Institute requests users not to make the products available for download elsewhere and to refer to marineregions.org for the most up-to-date products and services. A Terms of use is also available on the website. Internal funding has been sought to maintain the resource.

Lessons Learned

- Finding a business model that caters to commercial use that is also acceptable to a not-for-profit organisation may be difficult.
- Freemium models or commercial licensing require a level of knowledge about the commercial value of the assets that may be difficult to obtain due to information asymmetries.

For more information visit: www.marineregions.org

2.1.12. VRGS: Virtual Reality Geological Studio

Background

[1] See https://creativecommons.org/licenses/by-nc-sa/4.0/

[2] See https://creativecommons.org/licenses/by/4.0/

VRGS (Virtual Reality Geological Studio) is an integrated software solution to visualise, interpret and analyse 3D geological datasets of virtual outcrops, developed by Dr. David Hodgetts, formerly a Reader in Petroleum Geology and Reservoir Modelling, now CEO of VRGeoscience Limited.

VRGS was created as a research tool for the viewing and interpreting of Lidar (Light Detection and Range) data which was, at the time, the main way of digitally capturing the features of geological outcrops. However, it was designed to be accessible and usable by users beyond the creator – i.e. of commercial quality so that it could be used in industry (in oil & gas, mining, civil engineering etc). The software can also be used in academic geology research and teaching.

IP Developed

The intellectual property consists of the VRGS software (copyright).

Access Models

The aim was to increase the customer base within academic and commercial oil & gas markets (where it had gained an excellent reputation amongst a small number of users) and to penetrate new markets.

Whilst the original model was to achieve commercial success by means of a spin-out company that would licence / sell the software direct to customers, unfavourable market conditions in the oil and gas industry determined that this was too risky a strategy to pursue.

However, the recent availability of the e-lucid licensing platform, meant that the University of Manchester's Tech Transfer Office could test its value and sustainability in the marketplace without needing to seek external investment.

Based on the existing markets / users, a dual licensing strategy was pursued. For users in research institutions such as universities there was a small annual fee of £50 for academic licences. This particular academic licence strategy was important for two reasons: firstly, there was a well-established, career path of students / researchers in this field transitioning to the oil & gas industry and so product / brand awareness had value way beyond licensing revenue: and secondly, academic licences that were granted free of charge, did not generate feedback from users. Users are more likely to use a product and comment if paying a (small) fee.

Based on the fees commanded by equivalent products, commercial licences for use in industry were set at £6,000, with discounts for multiple or site licences and free, short-term evaluation licences also available.

Outcomes and Results / Project Sustainability

In approximately 4 years on the store VRGS was licensed c50 times & realised over £20K of revenue. Other, higher value licences, were negotiated and concluded offline.

Licence revenues were sufficient to allow David Hodgetts to take a career break to support further product development and in 2020 spin-out company VRGeoscience Limited was launched to commercialise VRGS.

Status of Research

The VRGS software is under continuous development, in many cases informed by the use cases and functionality requests presented by customers.

Lessons learned

Market-ready IP assets (usually copyright) of relatively low value (<£10K), but with the potential of high volume sales, are not typical of technologies traditionally encountered by university TTOs.

By automating much of the licensing process, administration costs are dramatically reduced to the point where a ROI can be achieved and in the long term revenues may be sufficient to support a sustainable business model.

An additional benefit is that a platform can facilitate the market validation of digital products – user feedback, organic sales growth – globally and with minimal costs. Over time, sales data can support the development of a business plan for spinning-out.

In this case the combined revenues allowed a spin-out to be created without needing to raise finance.

For more information visit:

VRGeoscience Limited
Contact Us (vrgeoscience.com)

2.1.13. Digital Heritage project ARMA: the Art of Reading in the Middle Ages

Background

The ARMA project was a collaboration between 8 institutions: 6 libraries a Museum and the Europeana Foundation. The libraries and the museum came together to create a collection of over 34,000 digitized reproductions of medieval manuscripts, early printed books and artefacts from their collections, general datasets and collections or editorials available on the Europeana platform[3], specifically covering the period from 500 to 1550 CE.

The main objectives of the ARMA project were -

1. Digitizing, pooling and placing online medieval manuscripts, books and objects to increase their visibility online.
2. To create educational content and enable knowledge sharing among curators and educators across Europe. Additionally, the project aimed at creating educational content focusing on teachers and primary, secondary and postsecondary students.

IP Developed

The original materials sourced and compiled in the project were medieval manuscripts, artefacts, and other early printed books that lacked any copyright protection given their medieval character and were in the public domain.

It is important to note that while medieval works themselves are not protected by copyright, the process of digitizing these works and the way they are presented can offer limited copyright protection with respect to aspects of the presentation of the said medieval content and not on the original medieval content itself.

Additionally new IP assets such as audio-visual materials, blogs and digital educational materials and tools were created in the course of the project implementation. The ownership of the said copyrighted content was held by the respective institutional creators.

Access Models

ARMA project realised its objectives by applying open creative commons licensing to all contents digitized, collated and created[4]. All contents developed were published on the Europeana platform.

The terms of use on the Europeana platform[5] explicitly state that:

1. All metadata are made available under Creative Commons CC0 1.0 Universal Public Domain Dedication[6].
2. All texts in blogs and exhibitions are licensed under CC BY-SA license[7].

It should be noted that the Europeana website does not allow commercial licensing through its platform. However, organizations using Europeana who want to retain and use some commercial copyrights can make the materials available elsewhere e.g., on their websites through commercial licenses.

[3] https://www.europeana.eu/en

[4] See https://www.medieval-reads.eu/docs

[5] See https: /www.europeana.eu/en/rights/terms-of-use

[6] See http://creativecommons.org/publicdomain/zero/1.0/

[7] https://creativecommons.org/licenses/by-sa/4.0/deed.en

Additionally, individual institutions shared their created content during the ARMA Project on their respective websites and institutional accounts on platforms such as YouTube. (See videos created by University of Leiden[8]).
NOTE: - To balance free public and royalty-bearing commercial use an owner might use a freemium model e.g., allow a low-resolution digital image to be freely downloaded, possibly also bearing a watermark and copyright marking; high-resolution images would require an application, approval and a signed licensing agreement making clear the terms of use before they were released.

Outcomes and Results

Seven cultural heritage institutions provided over 34,000 new digital versions of medieval manuscripts, printed books and coins to Europeana and updated and enriched another 31,000 items already available through the Europeana website.

Educational multi-media content was developed and shared to be used by curators, teachers and primary/ secondary students.

Status of Research/Project

ARMA -The Art of Reading in the Middle Ages was a Europeana Generic Services project co-funded by the European Union under the Connecting Europe Facility Programme. Running from 1 October 2020 to 31 August 2022, the project aimed to support European cultural heritage institutions by giving digital access to new medieval objects through Europeana. It also explored how these digitised items could be used in the classroom to demonstrate how reading culture in the Middle Ages became a fundamental part of European heritage.

Challenges and Lessons learned
The main IP challenges usually encountered in the archival projects by libraries, museums and collating platforms such as Europeana are: -

1. Prior right clearance of copyrighted content sourced and collated.
2. Individual institutional ownership and use rights of copyrighted content of sourced and collated.
3. Ownership and use rights of newly created copyrighted content during the project.
4. The means and operational business models available to provide wide community access.

The first challenge was addressed as the materials sourced were old and were in the public domain. The second and third challenges of ownership and usage rights of sourced copyrighted content and newly created multi-media materials by respective institutions (e.g., audio-video materials and other educational content) were addressed initially in the consortium agreement to make it as open as possible while each institution holding the respective copyrights on the contents created by respective institutions.

The key lessons can be thus summarized:

- When appropriate, museums and platforms such as Europeana must take proactive steps to ensure copyright rights clearance from respective owners before publishing or using on their platforms. (Note: Right clearance was not an issue in the ARMA project given the medieval character of the contents curated and the digitization process).

- The consortium agreement in the ARMA project explicitly mentioned licensing based on Creative Commons open licensing terms. (Note: The ARMA project was Europeana Generic Services project co-funded by the European Union under the Connecting Europe Facility Program.)

[8] See https://www.youtube.com/watch?v=CTlWxKCYUMY&t=270s

1. A Freemium business model might suit museums and universities who want to cover the costs of digitization and curation and/or to invest royalties back into research and educational activities.

For more information see:
https://www.europeana.eu/en
https://www.medieval-reads.eu/home
https://www.medieval-reads.eu/partners
Project Coordinador - Assist Prof Dr Ines Vodopivec, Project Coordinator

2.1.14. Using an AI Model to predict crop yield

Background to the example

University College Dublin (UCD) developed and trained an AI model on weather and soil data to assist in prediction of crop yield. The project was supported by Science Foundation Ireland (SFI) and aimed to provide valuable insights for agricultural productivity. The outputs of the project were required to be transferred to the licensee as part of a collaboration agreement funded by the licensee and SFI. Various sources of historical statistical data were used to train the AI model, including from private data brokers under tailed made data supply contracts. This was a critical issue as the data needed to be free of any ongoing copyright or other ownership encumbrances so that the derived data and outputs of the work could be used for commercial purposes. The University Technology Transfer Office was aware that this was a critical aspect for the project and worked to ensure that the data contracts were customised and rigorous to ensure that the results could be freely used for the planned purposes. This included training of an AI model but also the need to allow PhD programmes to be completed and for researchers to publish, while keeping some critical aspects of the technology confidential. The issue of confidentiality was strongly managed as universities typically find it a challenge to meet the legal requirements for keeping information confidential required under laws on 'trade secrets' e.g. in terms of the technical and procedural processes. This is important to the company as confidential aspects of AI models e.g. weights, epochs, and biases and the optimised hyperparameters are critical for competitive advantage and are not strongly protected by a patent. Special attention was therefore paid over the duration of the licensing agreement to consider what key features should be kept confidential. The Technology Transfer Office also investigated the issue of thesis embargo e.g. how long all or part of thesis could be kept off the open shelves.

Results

The work generated algorithms and parameters of an AI model as well as the associated training and test datasets developed to predict crop yield based on soil and weather data. The architecture, methods and algorithms were embodied in software that was maintained as confidential. The weights, epochs, and biases and the optimised hyperparameters of the AI model remain as confidential knowledge, as does the training datasets and the test datasets and the methodology around combining weather data and soil data for the purposes of the AI model.

IP assets and rights

Although the technology appeared patentable, a decision was made not to patent it due to the licensee's preference for confidentiality. The focus was on transferring the technology as know-how, (algorithms, parameters, datasets), ensuring some aspects remained confidential while allowing researchers to publish certain details.

Outcomes

- Successful transfer of know-how to the licensee under an exclusive licence in a specifically designed template licence that allowed access to know how as confidential information.
- As the licensee contributed much to the development, it was decided that royalties would only be payable above a certain threshold. The technology is currently being integrated into the licensee's platform.

- Embargoes and technical procedures ensured proprietary information remained confidential while allowing some academic publications.

Lessons Learned

- Various sources of data were used to train the AI model, including from private data brokers. Therefore, bespoke agreements had to be drafted and agreed such that any derived data from the data source was owned by the university and could be used to train any AI model for both academic and commercial use. It was also important to ensure that any Creative Commons (CC) licenses for public data that were accessed allowed for commercial use and for the data to be derived.
- Balancing commercial value and possibility to publish results of the academic research required involvement of Technology Transfer Officer as well as drafting some agreements in the initial stage of the project to maintain confidentiality while allowing necessary publications. In general, the Trade Secrets Directive is problematic for universities as they typically find it a challenge to meet the legal requirements required under laws on 'trade secrets' for keeping information confidential e.g. in terms of the technical and procedural processes confidentiality. PROs may be advised to refer to 'confidential information' rather than 'trade-secretes'.
- When using AI models a checklist outlining what key features can be kept confidential is useful.
- Because a PhD student had been involved it was important to understand the issues around a PhD publication embargo. Each university is likely to have different procedures around embargoing a thesis. It is important that the term of the licence does not exceed the length of period for which a thesis can be embargoed. Employed researchers should be made aware of their obligations using a Researcher Undertaking.
- Any relevant provisions around existing and emerging legislation e.g. the EU AI Act or counterpart US legislation need to be carefully considered.

Tools utilized:

- Custom agreements with data brokers
- Checklists to withdraw commercially valuable information from open publications.
- Confidentiality agreements and Researcher Undertakings.

Detection of Green-washing through AI-based Analysis

Background to the example

A team of experts in financial regulation, 'green washing' and analytics received funding from Enterprise Ireland to develop and commercialize a climate change mitigation greenwashing detection tool. This analyses the 'green' claims of companies worldwide and contrasts them with their actual emission performance.

Much of the data to develop such a model typically needs to be 'scraped' from the web[9]. This has implications because if copyright is attached to the scraped data then it may restrict use of both the data itself and derived data. The situation is changing rapidly with the development of legislation regulating AI. However, legislation also varies significantly between different territories including the EU, UK and USA. The US legal environment is currently more permissive than the UK and Europe regarding the use of copyrighted data due to the transformative fair use doctrine. But legislation in most other countries puts tighter restrictions on commercial use and this effects research that is then 'transferred' (commercialised).

The University Technology Transfer Office was aware that this was a potentially difficult legislative situation and were fortunately enough to have very specialised knowledge within the office.

Results

The technology developed thus far consists of a machine learning algorithm, with a claims analysis matched against greenhouse gases emission changes.

IP assets and rights

- Know-how, software, confidential information
- Copyright (in the software)) and potentially some patentable aspects.

Outcomes

- It is anticipated that the future beneficiary of the technology will be a spin out company that will sell insights to the financial sector around greenwashing.
- The business model is not yet, confirmed bur it is likely it will be one of AI as a Service (AIaaS) or Generative AI as a Service (GAIaaS).
- The project has developed a well-adapted AI management strategy.

Lessons learned

- While the project combined scientific research and plans for further commercialization the first issue the project faced was how to protect commercial valuable information while allowing publication of findings. The balance was found in consultations with the University TTO.
- US and EU and UK law varies significantly with regard to the use of 'scraped' data. The transformative fair use doctrine in the US allows users, under certain circumstances, to use copyrighted data without the consent or renumeration of copyright holders. Transformative fair use has been particularly important for the training of certain types of AI models with data. In Europe the situation is more complex. Article 3 of the Directive on Copyright in the Digital

[9] Web scraping, also known as web data extraction or web harvesting, is the process of automatically collecting data from websites and storing it in files or spreadsheets.

Single Market (CDSM) allows for universities and cultural heritage entities to perform Text and Data Mining (TDM) and scrape data, regardless of the rights of copyright owners, for the public good and for "research" purposes. In contrast Article 4 of the CDSM allows any entity to also perform TDM, however, they are not permitted to do so if the copyright holder reserves its rights. This may restrict transfer and use of any model from a publicly funded research team to a commercial company when it has been developed based on such data.

- In addition, Article 4 of the CDSM is the lynchpin for copyrights in the EU AI Act. This makes it complicated to commercialise research data and research teams need to be very aware of the implication of Articles 3 and 4 of the CDSM. Attention should be paid to how any data was scraped and whether copyrights holders' rights were maintained so that they will affect further use.
- There are provisions in the EU AI Act around how AI models deployed on the market are categorised from a rick perspective. and whether the AI model is "open source". Examples of applications classified as high risk would include, for example, medical devices utilising AI, along with critical infrastructure systems such as energy and water systems. High risk AI systems will need to adhere to significant compliance obligations. These include establishing a risk management system, providing accuracy, robustness and cybersecurity systems, ensuring data and data governance systems are in place, providing human oversight, ensuring transparency and the provision of information to users, and maintaining record keeping and technical documentation. A conformity assessment will be required before any high-risk AI system can be put on the EU market. Special obligations also apply around General Purpose AI (GPAI) models Taking into account the rapid development of AI legislation, teams basing their products on AI should be aware of these regulations and their changes through all the process of the project development, revising the IP strategy as they go forward as necessary. I
- The ESG (Environment Social Governance) sector is becoming heavily regulated. All new documents should be considered. This may require the involvement of professional lawyers.

Tools utilized:

- Internal guideline to see if the idea was suitable for commercial or non-commercial licensing.
- Tools and methods employed to scale, market, and valorise the result.

  Technology-adapted Invention Disclosure Forms (IDF).
- Confidential Information agreements.
- Internal database of all the legislation acts corresponding to digital products and AI usage (including Directive on Copyright in the Digital Single Market, EU AI Act, etc.).

2.2. Co-creation Case studies

2.2.1. Transparent Transportation

Background

Company A offers transportation services to citizens with special needs. These customers have a legal right to use more tailored and individual services than, e.g., public transportation. Thus, their customer segments vary, for instance, from young to old with different disabilities, such as physical, or mental health problems. Approximately 50 % of trips are made by customers over the age of 65.

The Company organises around 500.000 trips per year and most of these trips are ordered by calling its customer service agents. The total number of calls is around 400.000 per year. When everything goes smoothly, one phone call is enough to get customers from A to B in carpool-style. This is known as a 'routine call'. When, however, the car is late or the driver cannot find customers from the agreed spot, things get more difficult, and more phone calls need to be made.

The company wanted to find answers to the following questions:

How can we prevent customer service congestion and the resulting bad customer experience?

What kind of digital solutions are out there already or in the future that could help them reduce the calls in general but still help their versatile customers?

The company chose the co-creation model, facilitated by an independent entity. This increased the attractiveness of co-creation, because the facilitating entity brought a tested and validated operative model to the exercise.

The facilitating body selected the persons to participate in the joint development project. During the project, the facilitating body gave the members guidance and helped in decision-making. In addition, this entity ensured continuous communication with the Company.

Outcomes and Results

The main results were the compete re-design of the already existing ride-hailing solution. The team designed everything from ground up from accessibility in mind and thus transformed the way the service functions.

The main IP generated was the user interface design and the associated background material. The results were generated by a team of six university students where it was crucial for the partner to develop the next generation of their service

Exploitation of results and IP

After the end of the project the partner was automatically granted a non-exclusive license to the results; this was the default situation set out in the up-front agreement. This meant that the student team could do whatever they wanted as the owners of the IP. However, Company A wanted to secure exclusive rights to the results and decided to offer a lump sum of money to the team. The team accepted and shared the money according to their team agreement between the team members (in this case equally). Although there was no formalized process for this negotiation, the facilitator ensured a fair and transparent discussion where all parties were able to express their interests**.**

Status of Development

The result was further developed, fine-tuned and implemented into the daily operation by the Company in 2019.

Key intervention points and actions for transfer of the Good Practice (GP)

Intervention points	Stakeholder(s) involved	Critical aspects
The problem to be solved has been identified and defined	*Company*	*Co-creation activities are effective and projected.*
Contractual model before co-creation activities start	*Company, facilitator, co-creators*	*Clear agreements on IP, background material, and the scope of contributions ensure all parties understand their rights and obligations before co-creation begins.*
A decision according to the agreement	*Company, Co-creators*	*Negotiation point about the licensing of the solution, especially regarding exclusivity rights. Ensuring fair negotiation practices was crucial for a balanced agreement.*
Investments on further development	*All stakeholders with IP rights*	*A collective understanding of IP ownership, future investments, and freedom to operate is needed for further development and market deployment of the solution.*

Summary of GP transfer aspects

1. Participants in the co-creation should have a solid understanding of co-creation principles, joint development, and open innovation to contribute effectively.
2. The co-creation should only begin after all parties have signed an agreement or contract outlining the terms and conditions.
3. Contracts and agreements should be easy to understand and not serve as a barrier to participation, ensuring clarity on IP rights and responsibilities.

2.2.2. Maintenance and Augmented Reality (AR)

Background

Company B operates in the field of business automation, specializing in Virtual Reality (VR) and Augmented Reality (AR) solutions for factory automation and maintenance. The increasing interconnection of people, machines, and processes is transforming industries by optimizing the entire value chain, improving quality, productivity, and responsiveness, while reducing costs and maximizing profitability.

AR supports this transformation by enabling the seamless interaction of physical and digital elements in a real industrial environment and new user interfaces. This interaction is achieved with visualization devices such as smartphones, tablets, or smart glasses. Smart glasses, for example, allow operators to follow augmented instructions while keeping their hands free for practical maintenance tasks.

To explore these solutions and identify new opportunities, Company B initiated a co-creation project facilitated by independent intermediary. The facilitator organisation designs the co-creation project and recruit talented and motivated team of co-creators: a multidisciplinary team of five university students specializing in automation technology, media, software development, and social sciences.

The goal of the project was to design innovative concepts for using VR/AR technologies in factory maintenance context.

Outcomes and Results

Throughout the 10-week co-creation process, the team developed several demos showcasing how AR could be applied to maintenance tasks and industrial environments.

Company B provided background material (e.g., existing maintenance processes and technical guidelines) to the team, which was outlined in the contract and excluded from further IP rights or licensing. The students were responsible for designing and conceptualizing the new solutions to given context.

Created solutions included visualized step-by-step maintenance procedures and AR-assisted equipment checks. Results quality was good and approved by Company B. The team generated several concepts and demos, which could have led to RDI initiatives, invention reports or patents. However, these routes were not followed, as the focus was on exploring future potential and opportunities rather than formal IP protection.

Exploitation of results and IP

The small concepts and demonstrators of how to use VR/AR tech in factory maintenance had the potential to be patented. However, this route was not followed. Under the co-creation agreement, the Company got a non-exclusive license to utilize the results. The Company did not find the specific solutions useful immediately but used the process more to identify new talent from fields from which they have not previously recruited.

The results were not further developed or implemented by the Company at the time. Thus, the co-creation project largely brought indirect benefits to Company B, such as increased competence, avoidance of product development risks, development of technological maturity and application understanding. However, these benefits were not evaluated, and there is no accurate information about their development.

The team members themselves have not utilized or further refined the IP created in the project However, the wider value the team members got from involvement the project was significant.

Despite no formal licensing process being established for exclusive rights, the fair negotiation environment ensured that all stakeholders were satisfied with the outcomes.

Key intervention points and actions for transfer of the Good Practice (GP)

Intervention point	Stakeholder(s) involved	Critical aspects
Agreeing on access conditions for results at the beginning	*All stakeholders*	Avoid misunderstandings, misinterpretations and surprises at the end of the co-creation and post-co-creation phases
Tracking of emerging results and fair pricing	*All stakeholders*	Brings transparency and trust for all stakeholders involved co-creation.
Recruitment process	*Company, Co-creators*	*A situation where instead of direct IP rights, the activities focus on the transfer of know-how and experts. Is recruitment used as a tool to bypass IP rights?*
Knowledge transform during and after co-creation	*All stakeholders*	*Interaction during the co-creation process, development of understanding, exchange of background information and communication between stakeholders.*

Summary of GP transfer aspects

- **Clear IP Framework**: There needs to be a well-defined IP framework that distinguishes between company-provided background material and new, co-created solutions. This helps participants understand what is excluded from licensing rights and IP protection.
- **Transparent Access Agreements**: Co-creation processes should clearly define access conditions, including non-exclusive licenses and potential exploitation rights, ensuring all stakeholders have a shared understanding from the outset.
- **Knowledge Transfer**: The process must allow for clear knowledge transfer among stakeholders, ensuring that the co-creation team's expertise and insights are recognized as valuable, even when the solutions aren't immediately implemented.
- **Focus on Skills Development**: The co-creation process should support the development of both hard and soft skills for the team, especially in the context of working with industry professionals and practical applications like AR/VR solutions.
- **Recruitment and IP**: Special attention is needed to ensure recruitment is not used as a workaround to bypass IP rights or licensing obligations.
- **Outcome Evaluation**: Tools for tracking and evaluating indirect benefits and value, such as increased competence, avoided risks, and technological maturity, are necessary to assess the total value of co-creation.

2.2.3. Improved drug delivery system

Background

The co-creation project was part of an EU-funded academy-industry research initiative aimed at improving drug delivery systems. Some medical molecules currently require injection, which is not always ideal for patients. The project explored biomaterials and new medical devices that could deliver drugs through alternative routes, such as under the tongue, offering a more patient-friendly solution The research is still in the preclinical phase, focusing on new delivery methods for drugs.

The goal of the co-creation was to make the drug delivery device more user-friendly by utilizing iterative feedback from potential end users, aiming to design an alternative to injectable drugs.

The consortium included multiple academic partners, a university-affiliated research institute, SMEs, and pharmaceutical companies. The project was facilitated by independent co-creation experts. The team was composed of researchers from different fields, with the active involvement of an End-User Advisory Board (EUAB) consisting of people with lived experience (LE), specialists in patient involvement, and project coordinators.

Outcomes and Results

During the project, the team developed several advancements in drug delivery systems, focusing on devices that would allow for non-injection administration of certain medications. While the project is still ongoing, the early-stage prototypes and preclinical developments showed prove points by innovative drug delivering methods.

The project led to advancements in drug delivery devices and improvements in drug solubility. The IP terms were outlined at the start of the project as part of the collaboration agreement. No IP rights were allocated to the end-user members of the consortium, but their feedback and insight and was crucial in shaping the product.

The co-creation is ongoing. The researchers on this project are relatively new to co-creation and the involvement of people with lived experience. When they see the benefits, develop themselves and gain confidence in their collaboration with end users, it can be expected that co-creation will deepen over time.

Exploitation of results and IP

The consortium partners gained a non-exclusive license to utilize the project's outcomes. While there are no immediate commercialization plans, the project laid a strong foundation for future developments, allowing for potential IP such as patents if the product moves forward. The involvement of end-users helped shape the design but did not generate formal IP rights for those users.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Defining IP Rights Early	*All stakeholders*	*It is important to establish how IP will be managed from the start to avoid any confusion as the project progresses.*
Regular Reviews of Design Evolution	*All stakeholders*	*As the co-creation and solution design progresses, reviewing potential new IP opportunities, such as device patents, helps protect emerging innovations.*
Valuing End-User Input	*All stakeholders, end-user participants*	*Insights from the End-User Advisory Board contributed directly to product improvements and could generate IP opportunities.*

Summary of GP transfer aspects

- **Clear IP Ownership Structure:** With diverse contributors (academic partners, SMEs, pharma companies, and end users), there needs to be a transparent framework for IP rights that acknowledges both technical and user-driven contributions. End-user feedback should be treated separately from innovations they directly contribute.
- **End-User Involvement**: The feedback from end-users is critical, and it's necessary to distinguish between general user insights and actual innovative contributions that may shape the product. Thus, end-users need to understand their role clearly and whether their ideas could qualify for IP protection.
- **Confidentiality and Trust:** The consortium must establish strong confidentiality agreements (NDA) early in the process to protect both research findings and sensitive input from end-users. This ensures open communication and protects potential IP.
- **Consortium Coordination:** With multiple stakeholders from academia, industry, and end-user groups, coordination tools are essential. These should streamline communication and decision-making, and ensuring alignment between technical developments and user needs.
- **Flexible Licensing Agreements:** This case demonstrates that innovation may arise from unexpected sources (such as end-users), the licensing agreements should allow for flexibility in how different types of contributions (scientific or user-driven) are considered.

2.2.4. Wearable Technologies for smart car interiors

Background

As electric cars become more common, the automotive industry is going through rapid technological change. Cars are no longer just vehicles; they are becoming technology and software platforms that play a much bigger role in our daily lives. In this project, Company A, an automotive industry player, wanted to explore how smart sensors, flexible screens, e-ink, and wearable technologies could be used in the car's interior. The goal was to find new ways for cars to serve different purposes, such as a personal office space, entertainment hub, or even a living room on the go.

The goal of this project was to create visual concepts and demonstrators showing how future cars might use technologies like wearable devices, flexible screens, and e-ink to create new use cases for daily life. The target was to develop prototypes of wearable technologies that could be used in the interior design of cars to enhance the experience for car owners.

This co-creation project was facilitated by an independent entity that was responsible for recruiting co-creators and guiding the co-creation process. Co-creation team: Six university students from various fields like software development, usability, and media & arts.

Outcomes and Results

The main outcomes of the project were three different wearable technology prototypes that demonstrated how these technologies could work inside a car. These prototypes showed how future cars might serve as multi-use spaces for work, entertainment, or relaxation.

Exploitation of results and IP

During the project, Company A identified certain functionalities that they wanted to patent. The company decided to file invention reports for these ideas and paid the student team an invention fee as per their internal company policies. However, Company A did not acquire the full IP, allowing the student team to keep rights to parts of the solution that were not patented.

According to the agreement made before the project, Company A received a non-exclusive license to the results at the end of the project. This allowed the co-creation team to keep their rights as well. However, Company A wanted exclusive rights to specific parts of the results, so they offered the team a lump sum. The team accepted, and the money was shared equally among them based on their agreement. There is no further information about the development dur to strict information policy.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Licensing Decision (Before Project)	*All stakeholders*	*Decide on upfront licensing conditions.*
Results Evaluation (During Project)	*All stakeholders*	*Identify and map patentable or valuable innovations.*
Protecting or Patenting Decision (Post-Project)	*All stakeholders*	*Determine which parts of the project to patent*
Exclusive Licensing and Pricing (Post-Project)	*All stakeholders*	*Negotiate exclusive rights and fair acquisition fees.*
Post-Project Feedback (After Licensing)	*All stakeholders*	*Evaluate and improve the co-creation process, feedback and evaluation mechanisms.*

Summary of GP transfer aspects

- **IP Clarity:** Clear agreements are needed at the start of the project to define how IP will be handled and what rights all stakeholders have.
- **Patenting Decisions**: Tools are needed to help stakeholders identify which parts of the results are worth patenting, rather than assuming the whole solution needs to be patented.
- **Fair Negotiation of Rights**: After the project, it's essential to have fair negotiations for exclusive rights or patents. All parties should benefit from the results.

2.2.5. Developing new ways of lead generation in insurance industry

Background

Company A, a leading non-life insurance provider with the largest branch network in its region, sought to address a challenge: low market penetration for household property insurance. Despite the relatively low cost (around 50-60 EUR per year for a 60m² apartment), only about one-third of households were insured. Many individuals relied on post-incident support from municipalities or charity organizations, especially in severe cases like fire. The company's goal was to raise awareness of household risks and the availability of affordable insurance, while also understanding the barriers that prevented people from taking preventive action.

The co-creation process for this project was facilitated by experts from Demola and involved a team of six students with diverse backgrounds, including software development, finance, and user experience design. Company A, a leading non-life insurer, sought innovative ways to generate leads and raise awareness about household property insurance. The team was motivated by the challenge and worked closely with the company's representatives to develop fresh concepts for customer interfaces. The project lasted approximately 10 weeks, during which the students collaborated with end-users to validate solutions. Both the company and the student team signed agreements governing intellectual property (IP) rights, ensuring clear terms for access and potential payments. The co-creation setup emphasized collaboration, creativity, and a structured approach to IP management throughout the process.

Outcomes and Results

The co-creation process produced a new interface that allowed customers to manage existing insurance services and easily purchase new ones. The Company licensed the conceptual logic and graphical elements of this interface, which were developed by the student team.

However, an unexpected issue also arose: The company discovered that the graphical elements used in the final product had been sourced from third parties without proper communication or clearance. This could have led to significant legal problems if it hadn't been identified before full implementation.

Exploitation of results and IP

The company was satisfied with the outcome and acquired a license to use the conceptual logic and graphical elements of the interface. However, after integrating parts of the IP into their services, they realized that some graphical elements were 3rd-party-owned. This issue prompted discussions between the company, the student team, and the facilitator to resolve the situation.

The access model followed the pre-set co-creation agreement, where both the company and the student team were granted rights to the results. The company, however, had to handle the complexity caused by uncommunicated 3rd-party IP, raising concerns about managing IP rights effectively in co-creation projects.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
IP Auditing and Transparency (During Development)	*All stakeholders*	*The issue with 3rd-party materials was a significant problem that could have been avoided through ongoing IP audits.*
Clear Communication on IP Usage (Early Project Stages)	*All stakeholders*	*The use of 3rd-party content should have been flagged early on to avoid complications. Transparency in the source of materials is critical for avoiding legal issues.*
IP Ownership and Risk Assessment (Before Implementation)	*Owner of the IP*	*The company discovered IP issues only after starting to implement the solution. A formal IP ownership review before project completion would have helped avoid this risk.*

Key intervention points and actions for transfer of the Good Practice

- **IP transparency and clarity:** There needs to be a more structured approach to identifying and communicating the use of third-party materials within the co-creation process.
- **Regular audits:** Regular checks on both background IP (brought in by the team) and foreground IP (created during the project) are necessary to prevent legal issues.
- **Clear ownership structures:** Clear communication and documentation of IP ownership before any solution is integrated into the company's systems.

2.2.6. High-speed camera capturing for marketing

Background

Commercials are typically made by using traditional photography and videography. What if we could capture millions of images per second of anything, e.g. shockwaves? What are the opportunities in advertising industry when invisible becomes visible?

Company A was based in the field of research-intensive high-tech business. It offers unique laser illumination solutions for high-speed imaging and precise and continuous real-time monitoring. With our solutions, customers can visualize challenging processes of high brightness, e.g. welding or combustion, as well as processes with small and fast objects, e.g. droplets and ballistics. They were aware that, until recently, cameras speeds were only allowing users to capture the beginning and the end of certain processes; they were not able to capture what happened in between. Significant changes in camera technology had opened new opportunities for use e.g. the ability to capture the explosion of firecracker or popcorn kernel or critical moments in welding processes. The company wanted to obtain insights into the different domains where this new technology could be used in the media and advertising industry.

The company wanted to identify different use cases that could promote the opportunities offered by this technology. What might be the business opportunities if they could capture? What was currently 'missing'? Was there an existing need already that they were not aware of yet? What different phenomena could be captured with this technology?

Outcomes and Results

The project outputs multiple concepts demonstrating how high-speed camera technology could reveal previously unseen phenomena in consumer products, revolutionizing their marketing approach. The results were vital to Company A's future business strategy, highlighting the value of integrating their high-tech solutions into consumer advertising.

The results were ground-breaking for the partner's future business strategy and under the contract they had the right to exploit them. However, it was also clear to them that they didn't have the internal competences to exploit, regarding marketing expertise. After discussions with the student team, it was agreed to establish a joint venture to "spin-out" the consumer marketing focused business from the high-tech research business. This was a win-win situation where the team got to continue their work on the topic and the partner could bring the technology and some financial backbone for the newly established company.

Exploitation of results and IP

The main IP assets developed were the different use cases and consumer marketing concepts. The co-creation agreement granted both the company and the students non-exclusive rights to the results. After recognizing the commercial potential of the project, Company A and the student team negotiated to transfer these rights into the newly created joint venture, ensuring both parties could capitalize on the technology's application in consumer marketing. This joint venture facilitated the continued development and exploitation of the project's outcomes.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Joint Venture Anticipation	*All stakeholders*	*Identifying the potential for a joint venture at the beginning of the project to facilitate smoother transitions later on.*
Support for Establishment	*All stakeholders*	*Actively assisting in the formation of the joint venture as the project concludes to capitalize on the developed IP.*
Team Dynamics Assessmen	*Owner of the IP*	*Regularly evaluating team interactions to foster trust and collaboration among diverse stakeholders.*

Summary of GP transfer aspects

- **IP Management Framework:** A structured approach to managing IP rights and responsibilities in joint ventures to prevent disputes.
- **Technology Transfer Guidelines:** Clear guidelines for effectively transferring technology between different industries to enhance market applicability.
- **Multi-Disciplinary Team Formation**: Tools and strategies for forming and managing diverse teams to leverage varying expertise for project success.

2.2.7. Expanded broadcasting

Background

Company A, a major player in the media industry, sought to expand existing TV brands by engaging consumers in live television experiences. They were particularly interested in using the Second Screen Dimension to enable real-time interaction between viewers and live show content through their devices. Examples included live entertainment shows, sports events, and festivals. The goal was to create a solution allowing consumers to share their experiences and participate in the content. The ideal app would be free, platform-independent, and easy to use.

Co-creation activities was facilitated by external facilitator. They A assembled a team of four co-creators from diverse fields such as signal processing, UX design, and software development. Together, they worked to explore innovative solutions that would enhance live-show audience engagement and participation.

Outcomes and Results

The main result was a prototype AI-powered tool designed to sense audience reactions on Twitter (now X) during live shows. This tool analyzed audience sentiment in real time, helping producers and viewers gauge emotional responses as events unfolded. The intellectual property (IP) included the source code for the tool as well as development concepts for its further refinement.

Exploitation of results and IP

Company A signed a non-exclusive agreement with the facilitator, granting access to the project's results. Co-creators entered into a team agreement outlining their rights in terms of IP and licensing. This agreement also included provisions on potential payments for exclusive access.

Due to concerns that Company A's internal resources might not be agile enough to develop the solution quickly, the co-creators decided to form a start-up to continue the project. Company A agreed to be the start-up's first customer, offering the solution visibility in upcoming live shows.

Startup and Company A implemented proof-of-concept experiments. Service development and starup ended after these experiments. The IP has remained unused since then.

Key intervention points for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Joint Venture Anticipation	*All stakeholders*	Identifying the potential for a joint venture at the beginning of the project to facilitate smoother transitions later on.
Support for Establishment	*All stakeholders*	Actively assisting in the formation of the joint venture as the project concludes to capitalize on the developed IP.
Team Dynamics	*All stakeholders*	*Regularly evaluating team interactions to foster trust and collaboration among diverse stakeholders.*

Summary of GP transfer aspects

- **Clear IP Management Protocols:** Both the start-up and the company need structured protocols for managing IP when commercializing through external ventures.
- **Ongoing Support for Co-creators:** Structured support from facilitators and industry experts is necessary to guide co-creators through the early stages of start-up formation.
- **Agile Commercialization Routes:** Companies using co-creation need to consider flexible models, like supporting start-ups, to accelerate the development of innovative solutions.

2.2.8. Customer-Driven Innovation with IP Transfer

Background to the sub-scenario and illustrative examples

In this co-creation model, companies invite customers or external communities to participate in the innovation or product development process. By crowd-sourcing ideas, designs, and innovations, companies tap into the creativity of a wide audience. Intellectual Property (IP) in these cases is typically transferred from customers to the company, often in exchange for financial compensation or public recognition.

Several companies have adopted this approach, including:

- **Lego** with its *Lego Ideas* platform, where fans submit new product ideas that the company may develop and market.
- **Threadless**, a fashion company that provides customer-submitted designs for t-shirts and apparel.
- **Local Motors**, an automotive company that holds design challenges to crowdsource vehicle designs.
- **Quirky**, a platform for product inventions where users submit ideas for consumer products, and successful submissions lead to IP transfers.
- **Starbucks** with its *MyStarbucksIdea* platform, where customers suggest innovations in products and services, some of which are implemented by the company.

The commonality in these projects is their goal of reaching a large number of individuals. Typically, online platforms are used for this, which automate collaboration, information sharing and also contracts. It is typical that IP and rights are automatically fully transferred to the company in these crowdsourced co-creation examples. In addition, these are often campaign-type activities, without shared values or genuine cooperation.

Outcomes and Results

This type of co-creation produces very different types of innovation material and results that vary and are not uniform in quality. Some of the results can be completely worthless and wasted from the client's point of view, almost a kind of innovation spam. However, outcomes and results typically include the following three elements:

- **Product Innovation**: This model has led to the creation of new, customer-designed products, such as the *Women of NASA* Lego set or Local Motors' *Rally Fighter*.
- **Customer Engagement**: By giving customers a direct hand in the development process, these companies build strong community engagement and loyalty.
- **IP Monetization**: Customers who contribute to these platforms are often compensated through royalties (as seen with Threadless and Quirky) or other incentives.

Exploitation of results and IP

The primary exploitation of these co-creation models is through the acquisition of nascent and intangible customer IP. Companies use customer ideas as commercial products and innovations, leveraging the creativity of their communities without having to develop ideas internally. For example:

- **Lego** and **Threadless** acquire full commercial rights to customer submissions.
- **Starbucks** implements customer suggestions for improvements but doesn't always formalize the IP transfer.

- **Local Motors** and **Quirky** reward inventors with financial compensation or profit-sharing, in exchange for acquiring commercial rights to their designs.

This model also enhances brand loyalty and deepens customer relationships, which is an indirect benefit of co-creation.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Launching the crowdsourced co-creation campaign	Customer or consumers	Managing the large volume of customer submissions and ensuring a streamlined review and selection process.
When the customer submits an idea or other contribution	*Client, Customer*	Ensuring fair and transparent IP transfer agreements that satisfy both the company and the contributors.
Co-creatior engagement	*Client, Customer*	*Encouraging sustained customer engagement through incentives like royalties, recognition, and community involvement.*

Summary of GP transfer aspects

Identified requirements based on this case

- Clear IP transfer and licensing agreements that protect both the company and the contributors.
- Platforms that can manage large-scale customer interactions, voting systems, and innovation pipelines.

2.2.9. Industry-Academia and Startup Collaborations with IP Licensing or Acquisition

Background to the sub-scenario and illustrative examples

This co-creation model focuses on partnerships between companies and external entities such as startups, universities, and research institutions. These partnerships often result in the licensing or acquisition of IP, allowing companies to rapidly innovate without having to internally develop technologies from scratch.

Examples include:

- **GSK**'s *Open Lab* initiative, which encourages external researchers to collaborate on drug discovery for neglected diseases.
- **Procter & Gamble (P&G)**'s *Connect + Develop* program, through which the company acquires IP from external innovators to develop products like the *Swiffer*.
- **GE**'s *Ecomagination Challenge*, where the company invests in startup-driven technologies focused on sustainability and energy efficiency.
- **Unilever**'s *Open Innovation* program, which acquires or licenses sustainable packaging innovations from startups and research institutions.

Outcomes and results

The following outcome and result types are typical that the involving parties produce or gain in co-creation activities like this:

- **Accelerated Innovation**: These partnerships allow companies to quickly bring innovative products to market. For instance, P&G shortened its product development cycle by acquiring the *Swiffer* system through co-creation.
- **Shared R&D**: Collaborative efforts lower the costs and risks associated with research and development. For example, GSK's Open Lab collaboration on malaria treatments accelerated drug development while sharing research costs.
- **Sustainability**: Initiatives like GE's Ecomagination and Unilever's Open Innovation have produced environmentally friendly technologies, addressing global challenges like energy efficiency and sustainable packaging.

Exploitation of results and IP

The key outcome in this cluster is the acquisition or licensing of IP from external innovators. This allows companies to integrate cutting-edge technologies and solutions without investing in lengthy internal R&D processes. Some specific examples include:

- **GSK** licensing drug-related IP to bring treatments to market faster.
- **P&G** acquiring external innovations, as seen with the Swiffer product line.
- **Unilever** acquiring IP related to biodegradable packaging solutions.

By collaborating with startups, universities, and research institutions, companies gain access to innovative technologies that complement their strategic goals and/or create agility into their processes.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Launching the co-creation activities	All stakeholders	Establishing strong partnerships with external innovators and managing shared IP ownership.
Co-creation focus and scope defining	All stakeholders	Aligning the goals of the company and the external partner to ensure mutually beneficial outcomes.
IP and knowledge transfer	All stakeholders	*Developing systems for tracking the contributions of external innovators to ensure IP is correctly managed and compensated.*

Summary of GP transfer aspects

Identified requirements based on this case

- A robust IP management system that facilitates the smooth transfer or licensing of IP between partners.
- Collaborative platforms that enable seamless communication and data sharing between the company and its external co-creation partners.

2.2.10. Social and Non-Profit Co-Creation with Shared Knowledge or Open Innovation

Background to the sub-scenario and examples

Unlike corporate-driven co-creation models, non-profit and open-source communities focus on solving societal challenges through voluntary bases collaboration. Intellectual Property is typically shared under open-source licenses, allowing for free use and modification. In many cases, the goal is social good or the advancement of public services rather than commercial profit.

Examples of this co-creation model include:

- **Wikipedia**, a non-profit platform where users co-create content, contributing knowledge freely to the global community.
- **Linux** and **Mozilla Firefox**, open-source software projects where developers from around the world collaborate to build and maintain software.
- **Participatory Budgeting**, a public sector initiative where citizens co-create public services by voting on how to allocate a portion of public funds.

Outcomes and Results

The following outcome and result types are typical that the involving parties produce or gain in co-creation activities like this:

- **Shared Knowledge and Innovation**: Platforms like Wikipedia and Linux enable the global exchange of ideas, leading to continuous improvement of shared resources.
- **Community Ownership**: These models foster strong community involvement, where participants feel ownership over the co-created outcomes.
- **Social Impact**: Initiatives like participatory budgeting give citizens a direct role in shaping their communities, promoting transparency and public engagement.

Exploitation of results and IP

In these co-creation models, the emphasis is on **sharing** rather than owning IP. The Linux and Mozilla communities, for example, operate under open-source licenses, allowing anyone to use or improve the software. Similarly, Wikipedia allows free use of its content, encouraging global collaboration.

This model is less about commercial exploitation and more about the advancement of shared knowledge and public resources. However, there are still opportunities for companies or governments to capitalize on innovations generated through these collaborative efforts, for example by exploiting the results commercially under the Creative Commons license.

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Operating the co-creation activity at large scale	*Platform operator*	Ensuring sustained community participation and maintaining a high level of contribution quality.
IP and licensing policy	*Platform operator*	*Managing the governance and structure of open-source or non-profit collaborations*
IP and knowledge transfer	*Platform operator*	Developing mechanisms to protect the integrity of shared IP in an open-source environment.

Summary of GP transfer aspects

- Open-source licensing systems that ensure the proper use of shared IP and prevent exploitation by commercial entities.
- Tools to support large-scale collaboration across geographically dispersed contributors.

2.3. Crisis Case Studies

Unforeseen crisis

Unforeseen crisis situations include medical emergencies such as a global pandemic or a natural disaster (ND) such as a tsunamis, flood, earthquake and similar catastrophes. In such times there can be an acute and pressing need to make IP protected technology available very rapidly to alleviate the situation. This may be fully mature technology that is already being used or it may be technology that is developed in response to the situation. In both cases, the technology will need regulatory approval for use by an official organisation, e.g. the EMA in Europe, and be manufactured to stringent standards e.g. ISO9001 and associated ISO medical standards.

2.3.1. Rapid development and mass voluntary free licensing of the UCL Mercedes Ventura CPAP device: from first meeting to Regulator approval in ten days

Originator: University College London

Background to the initiative

In mid-March 202020 the COVID-19 pandemic was starting to spread. The number of people being admitted to hospital requiring help to breathe was rising sharply. While some patients needed to go on full ventilators, others would be helped if they could access non-invasive ventilation in the form of Continuous Positive Airway Pressure (CPAP) devices. Unfortunately the number of such devices was very low.

Aims and objectives and partners

A research group from **University College London (UCL)** joined forces with **University College London Hospital (UCLH)** and **Mercedes-AMG High Performance Powertrains** to respond to this need. Their starting point was an existing 'off-patent' CPAP device that had received regulatory approval in the UK many years ago, but was no longer being produced so there was little documentation to support manufacture. Using reverse engineering, including 3D imaging to produce 2D manufacturing drawings, Mercedes-AMG HPP and the UCL team were able to produce the blue-prints and plans needed to for mass production of the device.

Mercedes-AMG HPP had the high quality engineering expertise needed to produce the first devices. These were then rapidly tested by colleague at University College London Hospital on volunteers to produce the test results needed to seek regulatory approval.

Results and outcomes

The device was approved for use by the UK Medicines and Healthcare products Regulatory Agency (MHRA) 10 days after the teams first came together and Mercedes-AMG HPP started to manufacture 100 devices a day. After 4 weeks they had delivered 10,000 devices and demand was still rising from many countries.

Intellectual Property

The device was based on an expired portent but manufacture and use requires significant know-how.

Impact

The designs and manufacturing instructions for the device were released on Tuesday 7 April. As of May 2020, the team had approved over **1,850 requests from 105 countries** spanning Europe, Asia, Africa, Americas and Australasia. Many of these countries and teams were supported to manufacture and adopt through translation, manufacture and distribution. UCL-Venturas are now being used in 29 countries across the globe.

Access Model

The teams made the decision to license all the information needed to manufacture and use the devises free of charge. Download of all the information was subject to approval and made clear the special condition under which the regulatory approval had been granted, namely that the device was a non-CE marked CPAP, given approval for use in the NHS for the interest of public health protection under the Covid-19 pandemic emergency.

Prospective licensees had to meet certain conditions including having local regulatory approval in place, as required in the third party's own country and fully complying with any stipulated conditions, laws and regulations that ensure full patient safety. The terms and conditions also stated that the technical specifications for this CPAP were being shared for humanitarian purposes, to help support the international community addressing pressing demands to care for Covid-19 patients and that there was an expectation that those using these specifications to manufacture these devices would follow the same guiding principles and not seek for commercial gain. In addition, that that the instructions for manufacture should be followed precisely to ensure quality and safety, with no deviations or substitutions.

Application to license the device could be made online. Following human approval all documents and the licensing agreement could be downloaded from a website set up for this purpose. In the 2 weeks that followed release 1,080 downloads were approved and made from more than 100 countries.

Licensing T&C (Terms and Conditions)

Information needed to manufacture and use the device was only approved for organisations that met a number of criteria including their type and not-for-profit status.

Any manufacture and use of this CPAP by third parties required the third party to have local regulatory approval in place, as required in the third party's own country and needed to fully comply with any stipulated conditions, laws and regulations that ensure full patient safety. It was made clear that the instructions for manufacture should be followed precisely to ensure quality and safety, with no deviations or substitutions.

Support for manufacture and use

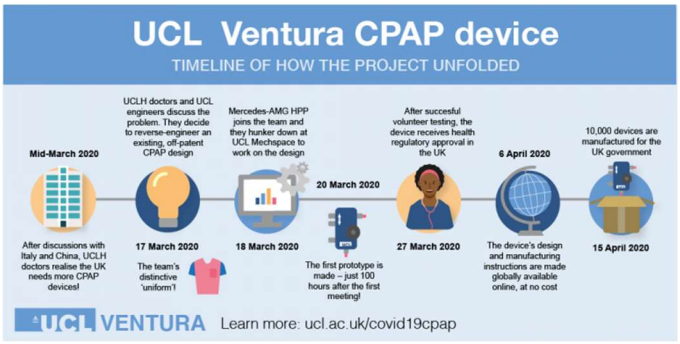
The basic information needed to manufacture and use the device was approved for download in conjunction with publicly available information. This included:

- Q&A webinar with the team to support international manufacture
- Q&A webinar on the clinical use of CPAP internationally
- Private Facebook page designed to offer informal space for teams in the process of manufacturing the UCL Ventura CPAP device. Teams could discuss any problems they have, any barriers to manufacture and/or any useful tips that may help others progress.
- FAQ of technical questions
- Instructional video of how to use the CPAP clinically
- Instructions for use of device clinically (written)
- Healthy volunteer test data (clinical)
- UCL Ventura device user manual
- Guidance for international use

Critical success factors

The UCL team highlighted a number of critical success factors in being able to offer the device for licensing so quickly.

- **Regulatory approval**: By starting with an 'off-patent device' that had previously been approved for medical use, the team needed only to demonstrate 'like-for-like' mechanical performance and the results of the volunteer trials.
- **High precision manufacturing capability**: By working with Mercedes-AMG HPP the UCL team knew that they could manufacture the device to the very high specifications demanded for medical devices.
- **Established relationships**: UCL had well established relationships with individuals at UCLH and Mercedes-AMG HPP. This meant that the teams could start collaborating in a highly trustful environment from Day 1
- **For more information visit**: https://www.ucl.ac.uk/healthcare-engineering/ucl-ventura-breathing-aids-covid-19-patients



Case Study 1 For more information see: https://www.ucl.ac.uk/healthcare-engineering/about-ucl-ventura

2.3.2. CSIC's SARSCoV-2 detection patent and the MPP: Voluntary free licensing via the patent pool

Originator: Spanish National Research Council CSIC

Background to the initiative

In 2020, the Spanish National Research Council CSIC filed for patent protection for COVID-19 detection test (EP20382495.8). This was developed by a team of CSIC researchers. The work was financially supported by the Spanish Government and Spanish Medicine and Medical Devices Agency who made it possible to undertake the clinical trials and manufacture the test ~~the assay~~ in Spain. Support was part of a broader initiative to build national capacity to manufacture vaccines in Spain. A license to manufacture the test-kits was signed with a Spanish company. However, this was not exclusive because the CSIC wanted to retain the option of having the technology used more widely.

In 2021 a representative of the CSIC attended a meeting of the European TTO circle and presented the license agreement to the wider technology transfer community. This brought it to the attention of the WHO and the MPP who suggested that the technology be licensed to the C-TAP patent pool where the MPP could help to broker sub-licenses with a focus on LMIC.

Results

Following discussions, a non-exclusive license to the MPP was signed on the 20th November 2021 with the right

'to sublicense to Third parties to encourage generic manufacture and the development of COVID-19 diagnostic technologies'.

Access Model

The licence to the MPP contains a number of notable clauses:

3. ROYALTIES

MPP will require Sublicensees to pay royalties on Net Sales of Licensed Products directly to CSIC on a country-by-country basis starting from the date of the first commercial sale of Licensed Products.

Royalties will be paid as described below:

A. Royalty-free for sales to any LMICs for use in any LMIC.

B. In HICs where there is a Patent Right granted and in force in the country of manufacture or sale, a non-creditable, non-refundable royalty of fifteen percent (15 %) payable on Net Sales in the previous calendar year and on a country by country basis and commencing on the date of the first sale of Product and continuing until the expiry of the last-to-expire Patent Right in such country.

C. In HICs where there is no Patent Right granted and in force in the country of manufacture or sale but where Licensee has used the Material for the manufacture of the Licensed Products, the royalty as described in 3(B) will be payable for a period of ten (10) years from the Effective Date.

5. KNOWLEDGE TRANSFER

The license foresees the need for know-how to flow from researchers at the CSIC to sublicensees. A commitment is made by CSIC to make knowledge available while any associated travel and out-of-pocket costs and are foreseen to come from Sublicensee with an acknowledgement that time and costs of KT will be minimised e.g. by electronic exchanges and allocating a sufficient and technically capable workload to knowledge transfer activities.

8. ASSIGNMENT AND SUBLICENSES

8.2. Licenses and sublicenses. MPP and CSIC will discuss and agree upon the identities of interested and suitable Third Parties to whom MPP shall grant sublicences for the purposes of fabricating and/or

commercialising the Product. ***MPP will require in the sublicences that sublicensee(s) use commercially reasonable efforts to ensure that the Product(s) be made available in LMICs at affordable pricing***. (Emphasis added)

TRANSPARENCY

The CSIC and the MPP also agreed that a copy of the Agreement as well as all sublicences may be publicly disclosed on the MPP's website.

It can be downloaded at: https://cdn.who.int/media/docs/default-source/medicines/c-tap/c-tap-mpp---csic-license.pdf?sfvrsn=6adf5560_1

Outcomes

This was the first experience of royalty free licensing for CSIC. But following this experience, the Research Council have mainstreamed clauses for LMIC into the Institute IP policy.

Lesson learned

- Avoiding an exclusive license and partnering with a medical patent pool can allow an institution to generate some royalties while also leaving the door open to produce significant wider impact from a medical patent.
- Making ethical/ responsible licensing part of an institutional policy opens the door to broader use of IP assets than economic gain.
- Working with similar groups e.g. Technology Transfer networks, can open the door to new opportunities.

For more information visit: https://www.who.int/initiatives/covid-19-technology-access-pool/csic-license

2.3.3. COVID-19 Compulsory Licensing – the case of Hungary and Remdesivir

While the concept of compulsory licensing received a great deal of attention during the COVID-19 pandemic there are few EU examples of compulsory licenses being granted. An exception was Hungary where the provisions on public health compulsory licensing were introduced into Hungarian law in 2020 as a response to the pandemic and where the trigger for a potential compulsory license is '**unmet supply needs in a health emergency situation declared under and as defined in the Public Health Act'.** An applicant must apply for and obtain a certificate from the Hungarian Intellectual Property Office (HIPO) as the national pharmaceutical regulatory authority.

In November 2020, Richter, a Hungarian pharmaceutical manufacturer, submitted applications for compulsory licenses for three patents concerning remdesivir. This is a drug, approved by the European Medicines Agency, for the treatment of some patients suffering from COVID-19 and pneumonia requiring complementary oxygen therapy. The HIPO granted the compulsory license one week after receiving the application. It was only valid for Hungary.

However, the patentee challenged the decision to grant a compulsory license in the Metropolitan Court, the Metropolitan Appeal Court, the Curia, (acting as the supreme court of Hungary) and finally, successfully, Hungarian Constitutional Court.

In October 2023, the Constitutional Court published its decision and annulled all the decisions made on the subject matter compulsory licence due to the violation of the Fundamental Law of Hungary. These decisions were based on whether fundamental law principles had been followed in the process of granting the license including whether the interests of right-holder had been carefully considered in fair proceedings.

The decisions were sent back to the HIPO with an instruction to re-evaluate whether the **preconditions for granting a public health related compulsory licence did in fact exist in 2020.**
The Hungarian Remdesivir case raises a number of interesting issues beyond legal process.

1. While the conditions for granting a licence were stated as '*unmet supply needs in a health emergency situation declared under and as defined in the Public Health Act'*, this proved difficult to demonstrate in practice. The patentee Gilead Sciences argued that they, and other companies in the Gilead group, had been supplying Veklury® (remdesivir) in fulfilment of orders placed by the Hungarian government under agreements concluded with Gilead at the European Union level. Hungary, as a Member State of the EU, was part of this scheme.

2. While there were Remdesivir shortages in the USA and other countries, and the price remained very high, Gilead Sciences blamed this on the complexity of the production process and the challenge of scaling it up. Gilead Sciences did not rapidly or strongly utilise out-licensing and left the impression that it would be hard for any other company to replicate the process successfully, possibly as a result as a need for trade-secrets that would not be available in the patent. However, Bangladesh is classified as a WTO Least-Developed Country, meaning that it is not required to offer patents on pharmaceutical products and Bangladesh-based companies including Beximco, independently recreated remdesivir and began selling it one month before any Gilead Sciences-authorized partners began production. In contrast to the $3,120 per treatment cost that the United States paid, Beximco's drug cost only $336 per treatment. Other Bangladeshi companies soon also began producing the generic, leading to a growing surplus that allowed Bangladesh to export fifty-thousand vials to six other countries by late July191 and to twenty-one countries by late August.

Equitable access involves not only **availably** but **affordability**. The Hungarian case may suggest that in some cases, compulsory licensing holds the key to both issues.

Preventable Crisis (Equitable Access)

Licensing technology to make it more accessible and affordable to LMIC is known variously as 'Global access' (Gates Foundation) 'Equitable access' 'EA' (MPP and Welcome Trust). Other terms that can cover aspects of this approach include 'Ethical access' and 'Socially Responsible access' (WIPO) and Impact Licensing (Université Grenoble Alpes).

Some definitions strongly overlap e.g. Global and Equitable, but in some cases e.g. 'Ethical access', 'Socially Responsible' and 'Impact Licensing', distinct differences are seen in rational and goal for policy change, the type of technology involved and culture of the country involved. In this document the term 'equitable access' has been used and the focus is on licensing to LMIC. Other PC actions that will be reflected in the tool-kit e.g. to encourage more Socially Responsible access have been highlighted.

2.3.4. Embedding EA into grant contracts: The Wellcome Trust

The Wellcome Trust is an independent global charitable foundation dedicated to improving health through research. The trust uses returns from its investments to fund further work, usually taking a 25% share in revenue and/or equity. In general, Wellcome does not receive donations or government grants and do not raise money from the public.

Equitable access is embedded in Wellcome Trust principals for funding. The organisation is committed to making the results of the research it funds 'affordable, appropriate, adapted and available, particularly in LMICs'.
Funded projects must all adhere to the Wellcome **intellectual property policy**, **equitable access to healthcare interventions statement** and **guidance on commercialisation agreements**.

The Wellcome Trust usually requires that grantees seek formal consent for commercialisation of results, giving them a very high level on control over the action. Companies must always obtain written consent before entering into transactions to develop or commercialise Wellcome funded IP, and bespoke revenue-sharing terms may apply. However, Wellcome waive this requirement for researchers working at not-for-profit institutions, under standard grant agreements, subject to certain conditions.

The Trust uses a number of mechanisms to help it achieve its equitable access goals. These include:

Contractual mechanisms

Contractual arrangements can vary on a case-by-case basis but some of the common ones used to drive EA include:

- Requesting or requiring that awardees have an appropriate and proportionate **global access plan** that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
- Tailored revenue-sharing arrangements to reward organisations that help deliver the Wellcome access ambitions.
- Stewardship plans outlining how to achieve the optimal use of an intervention.

Appropriate application of IP

- To improve health and support the sustainability of Wellcome funded projects, the management of IP rights by the award holder should incentivise innovation and support equitable access to it, being clear that different settings require different approaches.

- IP management will not preclude the ability to secure commercial rewards. Awardees may receive private benefit from exploiting Wellcome-funded IP, provided that health improvement remains the primary outcome and as long as the benefit is necessary, reasonable and proportionate, in line with UK charity law.
- Wellcome respects its awardees' and third parties' IP rights, which it expects to be applied appropriately to deliver public health benefit. If Wellcome believes that IP developed using Wellcome funding is being used in a way that restricts health benefit, then the Trust will work with the rights holder to ensure that the relevant IP is used appropriately. This might include **not seeking or enforcing patents in low-income countries, voluntary licensing with broad geographic scope in middle-income countries, and patent pooling**. In exceptional circumstances, such as IP being shelved or not taken forward for any reason, Wellcome will consider accessing the unexploited IP to deliver benefit in unserved countries.

Licensing provisions to address commercialisation agreements in low- and middle-income countries

Examples include:

- dividing up territories between a commercial and a not-for-profit partner
- providing for territories to revert to the institution if not commercialised by the commercial partner
- requirements for products to be supplied to low- and middle-income countries at or close to cost.

Promotion of transparency to support innovation and access to products

Wellcome also supports appropriate sharing of information to encourage innovation and broaden equitable, timely access. This is designed to create a better shared understanding of the relationship between the **costs of research and development, the price of products and appropriate levels of return**.

For more information see: https://wellcome.org/who-we-are/positions-and-statements/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions

2.3.5. Embedding Equitable Access into intuitional policy and practice: MPP and HEIs

A number of Public Research Organisations (PROs) have taken a significant step to embed equitable access into policy and licensing deals. This includes the addition of an AAP clause into their licensing agreements, developed in consultation with the MPP. PROs and their commercialisation units who have taken this step to-date include **Columbia University** (Technology Ventures), **University of California Berkeley** (Intellectual Property & Industry Research Alliances (UCB IPIRA)) **University of California, Los Angeles Technology Development Group (UCLA TDG)**, the **Innovative Genomics Institute** (IGI) and **Erasmus MC in the Netherlands.**

The approach can address equitable access through overarching institutional policy, licensing practice or a combination of the two. It is largely directed at exclusive licenses for drugs and therapeutics.

Policy statements

Policy statements indicate the need for "Global Social Responsibility" or “Humanitarian Access” or similar phrases in technology transfer of research results and in particular in licensing, to reflect the Mission of the institution and Not for Profit status.

Licensing Clauses

Embedding equitable access into licenses is seen as a way to give an overall EA policy approach ‘teeth’. By moving it from the overarching institutional policy direction into legal clauses it cannot be ignored and it encourages a collaborative approach with the licensee.

Typically, individual clauses address:

- Humanitarian Purposes
- Royalty free access in some territories
- Pricing transparency
- Affordable Action Plans (AAP)
- Progress and royalty reports

The AAP clause is a direct result of the work of the MPP and echoes approaches taken by the Gates Foundation (Global Access), Wellcome Trust (Equitable Access), CARB-X (Stewardship and Access Plan) and the CEPI (Equitable Access).

The AAP:

- Requires licensees to submit a plan of how they will achieve affordable access for the licensed product(s) in low- and middle-income countries, with strategies and timelines.
- Requires licensees to identify countries in which the licensee has no intention of commercializing.
- Only requires the submission of the plan when it is reasonably certain that the licensed product will be commercialized – i.e., within a specified amount of time of having received regulatory approval, which allows the licensee to focus energy and resources on the critical research and development activities needed to advance a technology and only develop the plan if/when the product is ready for market launch.
- Allows the licensor to call upon a “designated entity” with relevant public health expertise to assist in conversations with the licensee regarding the access plan.

Individual examples of how licensing agreements reflect equitable access including in some cases an AAP are shown below

- University of California, Los Angeles

University of California, Los Angeles

The **University of California, Los Angeles**' Technology Development Group (UCLA TDG) has implemented a practice of including in its patent license agreements to UCLA's biopharmaceutical innovations a provision requiring its licensee to provide and implement an "Affordable Access Plan" (AAP). The intent of the AAP provision is to encourage UCLA's licensee, if and when it receives U.S. Food and Drug Administration (FDA) approval, to develop and implement plans for supporting affordable access to the UCLA patented drug in low- and middle-income countries (LMICs), which plans may include collaborating with governments and non-profit organizations.

The AAP provision arose out of efforts among UCLA leadership regarding whether and how UCLA can play a role in ensuring that underserved communities in LMICs have affordable access to technologies originating from UCLA. UCLA TDG and the MPP had several collaborative conversations regarding the challenges university TTOs have had in identifying contract language of substance which would influence its licensees' behavior with regard to pricing and marketing strategies but not deter pharmaceutical partners from taking a license.

A review by the university of good practices led them to conclude that all of these reports stress that the primary goal of patent and licensing policies and practices is to maximize the further development, use, and beneficial social impact of these products. Revenue and profit should not be the primary motivation. The UCOP Guidelines note that '*developing successful practices is an evolving process, for an issue as complex as balancing access by developing countries to biomedical products with ensuring timely and appropriate development and commercialization of the product*.' If the approach is too prescriptive, licensees may be discouraged because of a perceived need to overcome too many obstacles in product development.

Initially the UCLA incorporated the following provision into their licensing agreements:

As part of its public mission to bring products to the marketplace, UCLA strives to enable underserved populations, which have limited access to adequate quantities of medical innovations arising from UCLA's laboratories, to have access to these innovative products. Licensees are encouraged to consider these populations' interests when marketing and selling Licensed Products.

While this language was well received by licensees during negotiations, UCLA leadership explored ways to improve it and to enable UCLA to have a material impact on the goals of ensuring affordable access to drugs originating from its campus.

As a result of discussion with the MPP the UCLA made the decision to add a further provision requiring its licensee to provide and implement an AAP. The AAP provision requires the licensee to identify shortly after receiving FDA approval:

- A specified set of low- and middle-income countries ("LMICs") in which the Licensee does not intend to commercialize the Licensed Products (the "Non-Commercialized Territory"); and
- Licensee's and/or its Sublicensees' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations.

The AAP provision also provides UCLA the ability to initiate discussions among its licensees and key stakeholders, such as MPP, who have the experience necessary to effectively enable affordable access

to LMICs. The hope is that by encouraging discussion and shining a light on these issues early in the licensee's marketing and commercialization plans, UCLA's licensees will be more apt to take steps to more effectively address affordable access issues.

To date, UCLA TDG has been successful in incorporating such a provision in its biopharmaceutical license agreements and has received minimal pushback from its licensees.

For a copy of the full AAP provision see Appendix A (page 6) at this link:
https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

- University of California Berkeley (UoCB) 'Humanitarian Purposes'

The UoCB now reflects EA into policy and license for 'Humanitarian Purposes' and this is clear in the **exclusive licensing template for therapeutics and diagnostics**.

Policy statement

As part of its public mission to bring products to the marketplace, the UoCB uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from UoC's laboratories, to have affordable access to these innovative products.

Licensing level

The UoCB now includes a Humanitarian license in its portfolio. This is completely distinct from the APP and was developed independently by the university.

Example exclusive license and relevant Humanitarian Purposes' clauses[10]

(Note that the UoCB is referred to in Agreements as REAGENTS')

2.5 "HUMANITARIAN PURPOSES" means (a) the use of LICENSED PRODUCTS and LICENSED SERVICES for research and development purposes by any nonprofit organization or other third party, anywhere in the world that has the express purpose of developing the LICENSED PRODUCTS or LICENSED SERVICES for use solely for protection from, treatment of, or diagnosis of Neglected Diseases in a Low- or Middle-income country as that term is defined by the World Bank (hereinafter "LMI COUNTRY(IES)"); and (b) SALE of LICENSED PRODUCTS and LICENSED SERVICES in LMI COUNTRIES at or below the cost of manufacture and distribution.

3.3. Humanitarian Purposes.

(a) REGENTS further reserves the right to license REGENTS' PATENT RIGHTS to any third parties solely for HUMANITARIAN PURPOSES. Such licenses for HUMANITARIAN PURPOSES will (i) expressly exclude the right of the third party licensee to export or SELL the LICENSED PRODUCTS from a LMI COUNTRY into a market outside of the LMI COUNTRY where LICENSEE has introduced or will introduce a LICENSED PRODUCT and where REGENTS' PATENT RIGHTS exist (such markets hereinafter the ''LICENSEE MARKETS") and (ii) require the third party licensee to create and maintain distinctive trade dress and trademarks that clearly distinguish third party LICENSED PRODUCTS and LICENSED SERVICES from LICENSEE'S LICENSED PRODUCTS and LICENSED SERVICES, (iii) require such third party LICENSEE's sale of LICENSED PRODUCTS and LICENSED SERVICES in such LMI COUNTRIES be at or below cost. For avoidance of doubt, such third party licensee may be permitted to export LICENSED PRODUCTS from

[10] See https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement.pdf

the LMI COUNTRY of origin to other LMI COUNTRIES and all other countries that are mutually agreed to by REGENTS and LICENSEE; and

(b) Notwithstanding the foregoing, prior to issuance of any such license to REGENTS' PATENT RIGHTS to a third party, REGENTS will notify LICENSEE of its intention to grant such license so that LICENSEE may have the opportunity to fill the anticipated market need itself and/or to engage in discussions for a sublicense with such third party in accordance with the procedures set forth in Paragraph 4.8. In the event any LICENSED PRODUCT SOLD in any LMI COUNTRY by any such third party according to the provisions of Paragraph 3.3(a) is exported, re-SOLD or otherwise introduced in any LICENSEE MARKETS, LICENSEE will provide REGENTS with written notification thereof, and if such exportation, re-sale or introduction does not cease within ninety (90) days after the date of such notice, then an amount equal to the retail price of LICENSED PRODUCT so exported, re-SOLD or introduced to such LICENSEE Market will be credited to royalties due to REGENTS hereunder.

4.9 **Affordable Access Plan**. Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide the REGENTS with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), LICENSEE agrees to discuss such reasoning with the REGENTS in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion the REGENTS concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to the REGENTS within three (3) months of such Initial Discussion. The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that the REGENTS can make available to third parties:

(a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory");

(b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and

(c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S.

Within thirty (30) days of the REGENTS' request (but no more often than once annually), LICENSEE agrees to confer with the REGENTS to review LICENSEE'S progress, and to consider in good faith any modifications suggested by the REGENTS, with respect to its Affordable Access Plan ("Progress Discussions"). For clarity, while the REGENTS may invite a designated entity to join either the Initial and/or Progress Discussions under this Paragraph 4.9, such discussions will at all times be made subject to the confidentiality obligations set forth in Article 25 (Confidentiality).

8. PROGRESS AND ROYALTY REPORTS

8.1 Progress Reports. For the period beginning [Date], LICENSEE will submit to REGENTS a semi-annual progress report covering LICENSEE's activities related to the development and testing of all LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS and the obtaining of necessary governmental approvals, if any, for marketing in the United States. These progress reports will be made for all development activities until the first SALE occurs in the United States. Each progress report will be a sufficiently detailed summary of activities of LICENSEE and any SUBLICENSEES so that REGENTS may evaluate and determine LICENSEE's progress in development of LICENSED PRODUCTS, LICENSED

SERVICES, and LICENSED METHODS, and in meeting its diligence obligations under Article 7 (Diligence), and will include (but not be limited to) the following: summary of work completed and in progress; current schedule of anticipated events and milestones, including diligence milestones under Paragraph 7.2; anticipated market introduction dates for the LICENSED TERRITORIES; status of implementation of the Affordable Access Plan and SUBLICENSEE's activities during the reporting period. LICENSEE also will report to REGENTS in its immediately subsequent progress and royalty reports, the date of first SALE.

- Columbia University - "Global Social Responsibility"

Columbia University has also independently developed licensing agreement to support EA under their Global Social Responsibility initiative. The university generally address the developing world health license issues by insertion of the following general statement as a separate paragraph into an exclusive licensing agreement for relevant technologies.

Section _- "Global Social Responsibility"

During the term of this Agreement, Columbia and Company shall take into consideration the principle of "Global Social Responsibility" in performing the various activities contemplated under this Agreement. "Global Social Responsibility" means facilitating the availability of (Licensed) Products in "Developing Countries" (as defined below) at locally affordable prices, under reasonable circumstances and terms to improve access to such Products in Developing Countries. "Developing Countries" means those countries listed by the World Bank as "Low-Income Economies," as such list may change from time to time. Solely by way of example, the Parties may mutually agree to ***revise royalty rates, adjust the fair market value, consider non-monetary consideration, and/or develop patent strategies in support of each party's dedication to Global Social Responsibility***. (Emphasis added).

For more detail see the full Exclusive License Agreement with Columbia University:
https://www.sec.gov/Archives/edgar/data/1514183/000121390024059821/ea020905901ex10-1_silo.htm

- Innovative Genomics Institute (IGI)

Part of IGI's mission is to make genomic medicines affordable and accessible to anyone who would benefit from them. A clear focus is on accessibility for low-income individuals living in the United States, and also on accessibility for individuals in low and middle-income countries.

In late 2021, IGI's Public Impact team, assembled a task force of 30 experts charged with first exploring **key drivers of high prices** and proposing alternative approaches to developing and deploying a genetic therapy that could reach more patients.

The IGI suggest a need to focus on 4 main issues:

Pricing: IGI have developed a dynamic cost-plus model for pricing new genetic therapies that could lead to a sticker price that is 10x less than genetic therapies on the market.

Organization and Funding Models: Besides for-profit corporations (C-corps), non-profit medical research organizations and public benefit corporations (B-corps) offer alternative organizational structures that could, in theory, reduce the sticker price. For these to be successful lower-cost capital (requiring a lower rate of returns) is needed to control costs.

Intellectual property: The IGI suggested that academic technology transfer offices (TTOs) can play a significant role in improving affordability and access via **licenses provisions and requiring access plans**.

Manufacturing: Manufacturing a genetic therapy to stringent regulatory standards is a key driver of cost. IGI has investigated various innovations, point-of-care manufacturing and regulatory streamlining that could lower prices while maintaining safety and efficacy.

For more information see: https://innovativegenomics.org/atf-report/

Other HEIs taking a very similar approach include:

- Erasmus Medical Center (Erasmus MC) the Netherlands

The approach at Erasmus University is partly shaped by the currently policy landscape of the Netherlands that has made 'Responsible access' part of their Global Health Strategy 2023-2030 and encourages the adoption of the 10 Principals for socially responsible licensing.

The EMC is committed to availability and accessibility of care in the region. They make an active contribution to the discussion on expensive medicines. For example, they look critically at the most effective use of (new) expensive medicines. In this, they seek cooperation with other hospitals and health insurers.

- NorthWestern University

See: https://www.invo.northwestern.edu/documents/invention-disclosure/therapeutics-startup-license-agreement-20190107.pdf

info@impac3tip.eu

www.impac3tip.eu

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