
Towards an Open Material Transfer Agreement
OPENPLANT IP WORKING GROUP REPORT

CONTENTS

EXECUTIVE SUMMARY

The OpenPlant Intellectual Property (IP) Working Group was formed to examine IP norms and policies that impede innovation in plant synthetic biology. The result was the development of the Open Material Transfer Agreement (OpenMTA), a legal tool for sharing DNA parts and other biological materials that allows IP-free sharing of foundational tools while promoting the scaling and commercialisation of novel advanced technologies.

OpenPlant is a collaborative initiative between the University of Cambridge, the John Innes Centre and the Earlham Institute in Norwich. It is a synthetic biology research centre focused on the development of open technologies for plant synthetic biology. As part of this initiative, the OpenPlant Intellectual Property (IP) Working Group was formed to examine current IP norms and policies that impede innovation in plant synthetic biology and develop pragmatic solutions.

The Working Group met at the University of Cambridge on 30 July 2015 to solicit input on the design specifications for an open material transfer agreement (OpenMTA), a legal tool that complements the BioBrick® Public Agreement and supports the sharing of DNA components as tangible material. The second aim was to gather and prioritise actionable goals for creating and sustaining an international platform of open technologies for plant synthetic biology.

This report provides background and context for our discussions then summarises the observations of the 23 participants, who included researchers, technical experts, and legal practitioners from academic, industry, and non-profit organisations.

The OpenPlant IP Working Group continued discussions through monthly calls and drafted several comment pieces and conference presentations. After extensive consultation, the text of the OpenMTA Master Agreement is published, initial signatories are invited and the first transfers of materials are beginning to take place, including transfer of bacterial DNA parts from Stanford University to the J Craig Venter Institute. Work continues to address the other issues identified in this report in the context of sharing OpenPlant-derived tools and technologies.

The authors welcome feedback on this report and invite suggestions for concrete actions enabling the creation and maintenance of platforms for sharing open biotechnologies.

For more information on the OpenMTA, see http://openmta.org

BACKGROUND TO IP & OPENPLANT

BACKGROUND

Synthetic Biology can be described as the design and construction of new biological entities such as enzymes, genetic circuits, and cells or the redesign of existing biological systems. This approach offers the prospect of reprogrammed biological systems for improved and sustainable bioproduction. While early efforts in the field have been directed at microbes, the engineering of plant systems offers the even greater potential benefits of complex metabolism, huge scale, and low costs.

OpenPlant is a UK Synthetic Biology Research Centre across over twenty groups at the University of Cambridge, John Innes Centre and the Earlham Institute, Norwich. We aim to promote innovation and social impact by accelerating the development and exchange of underpinning tools and techniques in plant synthetic biology, and to facilitate outreach, policy discussion and international development.

The liverwort *Marchantia polymorpha*, a tractable plant 'chassis' for synthetic biology. Credit: Jim Haseloff

OpenPlant incorporates several projects in trait engineering to produce applications of high value and societal benefit. These include improving the quality and yield of biofuels, animal feed, food and high value products through carbohydrate engineering. Other projects seek to engineer plant natural products with applications in drugs, agrochemicals, food and drink, cosmetics and other products.

OpenPlant workpackages focus on shared foundational technologies and their use for trait development. We promote a two-tier approach to managing intellectual property. Potentially valuable applications can still be patent protected in the conventional manner. There will be no change in practices at the top level. However we are exploring less restrictive models for distributing low-level tools and components for plant biotechnology.

As the scale of commercial biosystems are rapidly increasing, patent "thickets" and proliferating cross-licensing arrangements are becoming problematic, even for large pharma and agrochemical companies, and can be crippling for small companies. Innovation in a young field like synthetic biology requires freedom to operate. We believe steps to facilitate free exchange of DNA parts and tools will substantially speed the take-up of new technologies in plant synthetic biology, and foster innovation and entrepreneurship in the UK.

DEVELOPING OPEN TECHNOLOGIES FOR PLANT SYNTHETIC BIOLOGY

Synthetic biology requires a range of foundational technologies enabling engineering design principles to be applied to biological systems. These include computer modelling capabilities, libraries of characterised standard parts, and automation of lab protocols to enable high-throughput experimentation. OpenPlant aims to develop such tools and technologies in the liverwort Marchantia as a highly tractable plant 'chassis' for synthetic biology and then release these tools and technologies openly to promote

WE BELIEVE STEPS TO FACILITATE FREE EXCHANGE OF DNA PARTS AND TOOLS WILL SUBSTANTIALLY SPEED THE TAKE-UP OF NEW TECHNOLOGIES IN PLANT SYNTHETIC BIOLOGY.

PROVIDING RESEARCHERS WITH THE LEGAL TOOLS TO DISSEMINATE THEIR TECHNOLOGIES OPENLY IN A WAY THAT OWNERSHIP AND USAGE RIGHTS ARE CLEAR IS KEY

innovation. We will also produce systematic collections of experimental protocols and shared DNA parts in cyanobacteria, *Synechococcus elongata* and other plant and algal models. These parts will include novel markers, regulatory promoters, RNA-based gene regulation mechanisms and functional enzymes such as metabolic pathway components. Tools for efficient transformation, gene editing and shuttle systems will also be publicly released along with cell lines and strains of several organisms.

In addition to biological technologies, we plan to seed multiple small-scale collaborations for the use of the most recent miniaturised devices and software control for biological instrumentation. In particular, Cambridge has proved a fertile ground for the marriage of microelectronics, optics and biology in the past, seeing the birth of hybrid products like laser scanning confocal microscopy and Solexa/Illumina next generation DNA sequencing. OpenPlant will develop software for generating models, automating DNA assembly and quantification of gene expression as part of its core work packages and the initiative is additionally supporting over 100 small OpenPlant Fund grants over the next five years. These projects will yield a diverse range of open outputs that include low-cost and open source lab hardware prototypes, educational resources and more.

HARMONISING TECHNOLOGIES FOR PLANT SYNTHETIC BIOLOGY

The intention of OpenPlant is to promote innovation using a two-tier system for IP management. While freedom to operate is necessary for foundational technologies, the commercial applications and products that will be built upon these foundational technologies require investment in development, production and distribution for which IP protection is usually necessary. This two-tier model for IP management involves a decision about which route is most appropriate for a given technology to achieve its desired impact. Low-level technologies with little commercial value in isolation or with high potential to spur innovation are made available openly while high-value applications may be patented or otherwise protected.

Maximising uptake of OpenPlant outputs requires several legal, technical, and social components to complement the core technologies and DNA parts. As a good illustrative example, many OpenPlant researchers recently co-authored a common syntax for DNA part assembly (Patron et al., 2015) to increase interoperability of parts, thus complementing the freedom to operate provided by open or IP-free provision of the sequences and physical DNA. Technical solutions to storing and distributing part information are part of OpenPlant work packages, with registries based on the open source JBEI-ICE project to be provided at each OpenPlant partner site and linked to a network of other global registries.

Logo of OpenPlant, a UK Synthetic Biology Research Centre developing open technologies.

Providing researchers with the legal tools to disseminate their technologies openly in a way that ownership and usage rights are clear is also key. This involves training researchers on existing legal solutions as well as engaging IP and technology transfer professionals in developing new approaches and legal tools where none exist.

CURRENT PRACTICES IN MATERIAL TRANSFER

The transaction costs involved in acquiring and obtaining permission to use biomaterials present a significant logistical and legal barrier for academic research and for commercial development of biotechnologies (Walsh, Cho & Cohen, 2005; Ku & Henderson, 2007; Kahl, 2015). Although centralised repositories such as Addgene have helped streamline the distribution of biomaterials among researchers at academic institutions (Kamens, 2014), access to biomaterials remains problematic for researchers at for-profit institutions and for those wishing to develop commercial applications.

The contractual obligations imposed by standard material transfer agreements (MTAs) in use by many academic institutions and centralised repositories allow access only by researchers at academic or non-profit institutions and do not allow sharing of biomaterials outside the identified laboratories or use of biomaterials for commercial purposes. Moreover, any variance from these standard terms must be negotiated on a case-by-case basis.

From a technical perspective, MTAs and the transaction costs they entail for access and use of biomaterials has had a negative impact on research. Researchers in both academic and commercial institutions have reported delays in their research, abandonment of ongoing projects, and the inability to embark on new projects due to difficulties in negotiating terms for access and use of biomaterials (as demonstrated in the SB6 State-of-the-Art Survey).

From a legal perspective, MTAs are problematic in that their terms may expand the rights of an institution well beyond those granted under formal intellectual property laws (Bubela et al, 2015). For example, MTAs may impose obligations that limit the use of materials that are not eligible for patent protection or for which patent protection has expired. MTAs also may limit the use of materials in countries where the inventors or owners have not sought or been granted patent protection. And most worrisome are terms within MTAs that attempt to "reach through" the agreement and lay claim to ownership of or returns from any future tool or technology developed using the materials.

In the field of synthetic biology, many researchers rely on registries of biological parts as a community resource for sharing biomaterials and associated data (Kahl & Endy, 2013). The idea is that contribution, use, and re-contribution of genetically encoded functions will create a positive network effect that will enhance the value and sustainability of these common registries. However, to enable the synthetic biology research community to realise these positive network effects, a new standard material transfer agreement is needed that will provide access to biomaterials for all researchers and will encourage commercial development of foundational biotechnologies

The Open Material Transfer Agreement (OpenMTA) is our proposed solution. A simple, standardised legal tool that enables individuals and organisations to share their materials on an open basis. The primary purpose of the OpenMTA is to eliminate or reduce transaction costs associated with access, use, modification, and redistribution of materials. This in turn will help minimise waste and redundancy in the scientific research process and promote access to materials for researchers in less privileged institutions and world regions.

Synthetic biology approaches require many DNA components on a scale that can result in large transactional costs when sharing DNA and other biomaterials. Image: DNA Lab by University of Michigan School for Environment and Sustainability on Flickr, licensed under CC-BY 2.0.

PRINCIPLE GOALS OF THE OPENMTA

Eliminate or reduce transaction costs associated with access, use, modification, and redistribution of materials.

Minimise waste and redundancy in the scientific research process.

Promote access to materials for researchers in less privileged institutions and world regions.

FEATURES OF THE OPENMTA

ACCESS

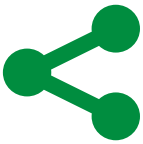
Materials available under the OpenMTA are free of any royalty or fees, other than appropriate and nominal fees for preparation and distribution.

ATTRIBUTION

Contributors may request attribution for materials distributed under the OpenMTA.

REUSE

Materials available under the OpenMTA may be modified or used to create new substances.



REDISTRIBUTION

The OpenMTA does not restrict any party from selling or giving away the Materials, either as received or as part of a collection or derivative work.

NON-DISCRIMINATION

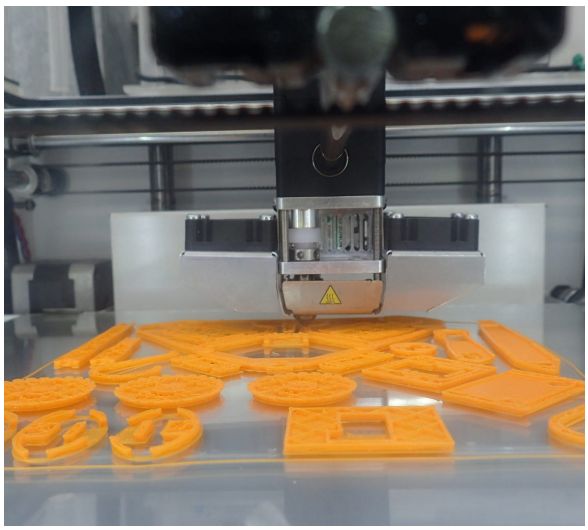
The OpenMTA supports the transfer of material between researchers at all types of institutions, including those at academic, industry, government, and community laboratories.

WORKING GROUP DISCUSSIONS

Need for an Open MTA

Early discussions addressed the current state of patent protection of DNA parts and the need for an open MTA. One participant asked if a patent landscape analysis had been completed - is there clear precedent for composition of matter claims for DNA parts in the patent literature and a clear need to make them more openly accessible? This was flagged as a potential study to take forward, although as presented in the introductory material there is anecdotal need documented from synthetic biology researchers.

The example of mobile phone components was raised as a space where standards and liberal licensing were viewed as essential to allow interoperability and technological innovation. Synthetic biology was thought to be in a similar situation given the sheer scale of parts. As one participant put it, we may now be talking about 10-20k parts but how will the legal and social system cope with 2 million parts - what will happen to people's willingness to share if we see a linear or exponential growth in parts and their monetary value increases? One synthetic biologist suggested that there will be a non-linear explosion of parts but these will be segregated by organism and



Sharing of 3D-print designs was raised as an example of sharing practices that could be relevant to synthetic biology. Credit: SynBio SRI, public domain image under CCZero waiver.

limited by the finite number of genetic elements available, but no participants responded to the question of shifting incentives and community buy in given this trajectory. It was suggested that we may be able to learn from other communities that have developed an ethic of openness and sharing, for example in software or hardware, with the specific example of 3D printing files.

Others participants were interested in current thinking around scope of an open MTA and whether the intention was to provide a legal tool for synthetic biology and DNA parts specifically or for biological materials more generally. They were also interested in the extent to which an open MTA was the only option on the table and whether other suggestions could be discussed. The following alternatives to an open MTA were then raised by the group during the course of the meeting:

- No legal mechanism - focus on technical solutions to remove barriers to reuse of materials
- Set up a system of bio-engineers' rights akin to plant breeders' rights
- Give all IP rights away.

In discussing the need for new legal tools in this space, several synthetic biologists pointed out that an open MTA is just formalising a practice that already exists as many labs use materials either without going through an MTA process or not strictly adhering to the agreement. There was also a feeling that technical solutions might be more valuable in facilitating sharing, for instance better DNA part repositories.

Several participants felt that a legal tool was an important solution, but that existing frameworks could be co-opted from within plant science, particularly if the focus was on plant synthetic biology. Plant Breeder's Rights (PBRs) provide a two-tier system like the proposed open MTA, whereby breeder's have exclusive control over the propagating and harvested material of a new, stable plant variety for a number of years, but protected varieties may still be used by others for breeding and experimental purposes. It was suggested we might borrow from this model to set up a system of bio-engineer's rights that protect the material as an alternative to patents. Some of the benefits would be sharing biomaterials in a way that is already deemed suitable and allows for innovation and

Plant Breeder's Rights (PBRs) also provide a two-tier system of IP, whereby breeder's have certain exclusive rights, but the material can still be used for breeding and experimental purposes. Workshop participants suggested setting up a system of ' bio-engineers' rights' Image: Wheat by Brett Jordan on Flickr, licensed under CC-BY 2.0

variety. Legally, as long as the biological part or material is a living thing that has to be maintained it can be analogous with plants in terms of breeding rights, although it is unclear the extent to which DNA falls into this category. As PBRs are already used in a non-institutional context, they may also more easily translate to sharing outside of academic institutes e.g. between biohackers.

Those who advocated during the meeting for giving all rights away felt that an open MTA does not go far enough in dedicating the materials to the public domain in perpetuity. For this to happen, a non-assert clause is required which obligates those originally making the material available not to assert IP rights over it. Such a clause is not usually included in an MTA although it could be added and it was suggested that linking to the BioBrick® Public Agreement (BPA) might assist with clarity over rights to the 'design' of the part, which are legally separate from those covering the physical material.

In order to surface further ideas around the OpenMTA as presented and explore other solutions, a non-exhaustive list of ideas for creating and sustaining an international platform for sharing open biotechnologies was solicited from the meeting participants. This list includes inputs for the design specifications of the OpenMTA as well as potential technical solutions and social considerations that address the broader legal, technical, and community aspects of creating and sustaining open biotechnologies.

The construction of this list led to a range of themes emerging which are discussed in this report.

WORKING GROUP IDEAS & CONCERNS

Identifying and prioritising ideas

The list of ideas provided by participants is shown in Appendix 1 and is rank-ordered based on the type of idea (legal, community, or technical) and the priorities assigned by meeting participants. In creating this list, meeting participants first articulated their ideas to the group and then wrote these ideas onto large flip charts. Participants then used up to five post-it notes to designate the ideas they considered high priority and to specify why they considered those particular ideas important. Several observations are of note:

Some participants felt strongly that there should be a mechanism to give away all rights in the materials in perpetuity (one person cast three votes, another person cast all five votes, and four people cast one vote). One participant commented that "this point should continued to be made and asked", suggesting that even those who may not feel it is a viable or preferred solution appreciate it as a benchmark or comparator for other options that retain some rights. The point raised questions within the meeting about what public domain means, the extent to which it is possible for materials to enter it and the basis of design decisions for an open MTA.

There was a clustering of ideas around the importance of building and educating the community. For example, six votes were placed on the importance of building a community and five votes were cast for creating an educational resource and FAQs on MTAs. Participants highlighted the creation of a "culture" and a "moral economy" and comments on education included the current lack of understanding of MTAs and a "mistrust" of agreements. Several votes were cast for ideas around branding of the proposed open MTA to make it recognisable and increase awareness and uptake.

There was also a clear desire for technical solutions that would make it relatively effortless for researchers to participate in contributing DNA parts to an open platform. One participant described ease of use as "paramount" and another linked the idea that if we are asking scientists to "give away" their work then this shouldn't involve work on their part. Others reiterated the transactional costs to institutions and the idea of reducing these, particularly as several participants predicted a large rise in biomaterial transactions occurring. Four votes were cast to implement a "one click" licensing solution and one participant stated "I don't want to talk to anyone or fill out a form. I want it to be instant".

A common thread through several conversations throughout the day was a recognition that the proposed MTA is not suitable for all parts, purposes or parties at all times but it introduces choice into the technology transfer decision process. However, it also became clear that there was a great deal of confusion about the features of an open MTA and how it would work in the context of other legal, technical, and community initiatives. These concerns have been summarised in the thematic sections below.

Redistribution

The main concerns raised around redistribution focus on the ability for the recipient to:

- Edit the part
- Redistribute the part to any party
- Allow commercialisation of the part.

To further clarify, the proposed design for an open MTA enables recipients to duplicate and redistribute parts to commercial, academic or non-commercial recipients, thus allowing DNA synthesis companies to freely manufacture and distribute parts. The ability to modify a part and subsequently place restrictions on that novel part is also possible, making it non-restrictive for any party who wishes to sell or redistribute. Making commercial use explicit in the wording of the MTA was suggested by at least three participants and commenters as preferable to the implicit allowance through describing allowed us as 'for any lawful purpose'

Several concerns were raised about redistribution and associated mechanisms. One was that a practice may emerge by which someone put restrictions on a part that they had only modified slightly, which would be allowed by the proposed open MTA. This was not viewed to be a problem by some in the room and indeed encouraged as the original part would still be available. Another

Commenting and voting on ideas for open MTA design goals at the IP working Group Meeting. Credit: Jenny Molloy, in the public domain under a CCZero waiver.

participant suggested this could lead to "scams" if people were unaware of the existence of the free version. A distinct but related point was also raised around actors distributing material that was not as advertised or even dangerous. Liability for losses associated with this action could represent a problem for creators and intermediary distributors. No clear solution was raised to this but it was noted that such actions are already possible under the current system.

It was suggested that the two concerns above and broader issues of awareness of freedom to operate and quality control could be addressed in part by widely distributing information on the free parts via a public repository or registry, which potentially allows feedback on parts. This led to substantial discussion, including data protection implications of such a database. At this stage, it was important to reiterate the distinction between the information representing the part (i.e., the DNA sequence) and the physical material (i.e., the DNA itself contained in a vector or other distribution format). An MTA focuses purely on the transfer of material, not information. This raised a concern over whether the cost of *de novo* synthesis of DNA would soon compete with the cost of redistributing physical DNA to the point where no-one transfers materials anymore but only the information. Will an open MTA be obsolete soon after it is created? Some synthetic biologists confirmed that they currently sometimes synthesise rather than request parts from other labs and see this practice increasing. However, other synthetic biologists highlighted that the field is becoming more ambitious in the length of the DNA parts they create, including building chromosome scale fragments, and it is unclear how well synthesis technologies will keep pace with this. Others pointed out that other materials such as chassis lines cannot be synthesised so MTAs will still be required.

The final concern raised on redistribution was the associated transaction cost of maintenance and postage of physical DNA stocks in addition to the cost of administering MTAs. Who will face these costs and how much of problem do they represent to the recipient or redistributor? No one in the group was aware of any empirical data for how much time universities and individual labs currently spend negotiating MTAs and physically preparing DNA for redistribution. Several synthetic biologists in the group used third party distribution services such as Addgene, who currently redistribute material under the UBMTA. OpenPlant plans to use the Arabidopsis Research Centre, GARNet and other plant-specific repositories to assist in redistribution. This increases the range of organisations that could be persuaded to offer material under an open MTA. Repository agreements to use the new MTA were deemed to be important by some participants, with three votes for establishing them as a priority and comments that they were "important for uptake/dissemination of parts from academic communities" and that "an open MTA should be functional without us establishing a repository."

The transaction costs involved in maintaining and redistributing DNA stocks are high. Credit: Red Dot by Sarah Laval on Flickr, licensed under CC-BY 2.0

Attribution and Reuse

Discussions around reuse of materials under an open MTA focused on concerns about provision and tracking of attribution, primarily in academic institutions and this was considered to be a key part of creating a community culture. Several participants suggested that this needs to be considered alongside the role of publications and patenting in institutional and national contexts. The incentive structures that exist for researchers can be very different across these parameters and several descriptions were given of less or more permissive technology transfer regimes in different institutions.

Understanding the motivations for making things open and how different people want to be rewarded was raised – as one participant put it, "the sense of 'mine' drives a lot of work in general". Solidifying trust and reputation was raised as a key driver and regulator of academic work, but may be less important to those operating outside academia. Overall, participants suggested that consideration should be given to:

- Creating a system to allow attribution of the part to be awarded to the correct individual.
- Tracking of attribution, although the question of whether this should be mandated or left to scientific community norms had a mixed response and no clear preference emerged.
- Implementing a feedback mechanism enabling work to remain open after redistribution but enabling attribution to remain with the original contributor of the part.

Suggested solutions included an online maintained repository of parts with provenance information. The idea of unique identifiers for parts, individual creators and publications was raised, which would enable cross-linking of information without losing this provenance trail using a concept that is already widespread in the biosciences and familiar to researchers e.g. GenBank IDs for DNA and ORCIDs for individual researchers.

Concerns were also raised around quality control and its link to reputation. One idea focused on classifying work as private on the repository to indicate that it's in progress but the part is not yet ready for open distribution. This was suggested to fit well into a triage structure, whereby researchers make an active decision about whether to release openly that may come at various points in the part creation process. It also fits with existing practices in the iGEM registry, which contains theoretical parts that have not been generated yet.

From a legal perspective, such a database could also address concerns that materials might have IP claims of which redistributors are unaware. It was suggested that removing some of this uncertainty may enable higher flux of materials. The database would also form a resource for patent examiners in the course of searching for prior art and could therefore be opened up to material not under an open MTA with clear marking.

5'---ATG GTA TCC CGT AAG GCT GTG GCT GCT CTG CTG GTG GTG CAT GTA
GCT GCC ATG CTG GCC TCC CAG ACG GAA GCC TTC GTC CCC ATC TTC
ACC TAT GGC GAA CTC CAG AGG ATG CAG GAA AAG GAA CGG AAT AAA
GGG CAA AAG AAA TCC CTG AGT GTA TGG CAG AGG TCT GGG GAG GAA
GGT CCT GTA GAC CCT GCG GAG CCC ATC AGG GAA GAA GAA AAC GAA
ATG ATC AAG CTG ACT GCT CCT CTG GAA ATT GGA ATG AGG ATG AAC
TCC AGA CAG CTG GAA AAG TAC CCG GCC ACC CTG GAA GGG CTG CTG
AGT GAG ATG CTT CCC CAG CAT GCA GCC AAG---3',

An example of a DNA sequence cited in a patent. A database of open DNA could form a resource for patent examiners in the course of searching for prior art.

Non-Discrimination

Some expressed confusion about what was meant by "Non-discriminatory Access" and wanted to be sure that an open MTA did not focus on big institutions but also would enable access by DIY labs, hackerspaces, etc. To clarify, the intention is for an open MTA to support material transfer for individuals at all at all types of institutions, including those at academic, industry, government, and community laboratories. Therefore, the proposed MTA does not include any provision that would require the recipient to be associated with a specific type of institution (e.g. a requirement that the receiving organisation be an academic or non-profit institution). To avoid confusion in the future, it may be best to label this feature "inclusivity" rather than "non-discrimination", although non-discrimination is the term used in other open licensing initiatives such as the Free Software Definition, Open Knowledge Definition and Creative Commons licensing scheme.

The group questioned the non-discriminatory clause, as previously reported in discussion on what rights could and should be given away.

Institutions

The proposed open MTA is intended to work in existing institutions in a way that doesn't cause disruption and makes MTA transactions easier for contract offices and material donors and recipients. Quantitative data is not available but our understanding through anecdotal evidence is that MTAs account for a substantial workload in the contracts offices that deal with them. In particular, any negotiations with companies absorb a lot of time. Much of the due-diligence work takes place the first time a material is transferred, but under the current system each subsequent transfer requires individual signing of the agreement and negotiation if the UBMTA is not used or the recipient is a company. We discussed the following ways to minimise the burden on institutions:

'One-click' electronic agreements: Electronic UBMTAs are already implemented by Addgene and are likely to be acceptable as long as they fit into the administrative workflow. Participants commented that speed and ease of use is paramount and vital to the success of any open MTA.

Pre-agreement to open MTA terms: the proposed open MTA will not require re-negotiation for companies and therefore in principle it should be possible for the institution to agree that something can be sent out under an open MTA once and then provide a single-click license for recipients that still allows sufficient information for institutions to track usage for their own record-keeping. This will be a substantial departure from current practice and may be challenging to negotiate, particularly in institutions with a greater mandate to protect any potential future intellectual property rights in the materials. It is likely to be less challenging at Stanford and Cambridge where researchers have more autonomous control over the use of their research outputs.

Providing software and links to allow tracking of parts: For academic exchanges, institutions may use MTAs as a tracking mechanism as much as a legal tool and therefore other ways of tracking reuse of parts and materials will aid in any transition to use of an open MTA, where there is potential for that ability to be lost given the recipient's right to redistribute. This was also emphasised in the discussion on research incentives and barriers to use of open MTAs.

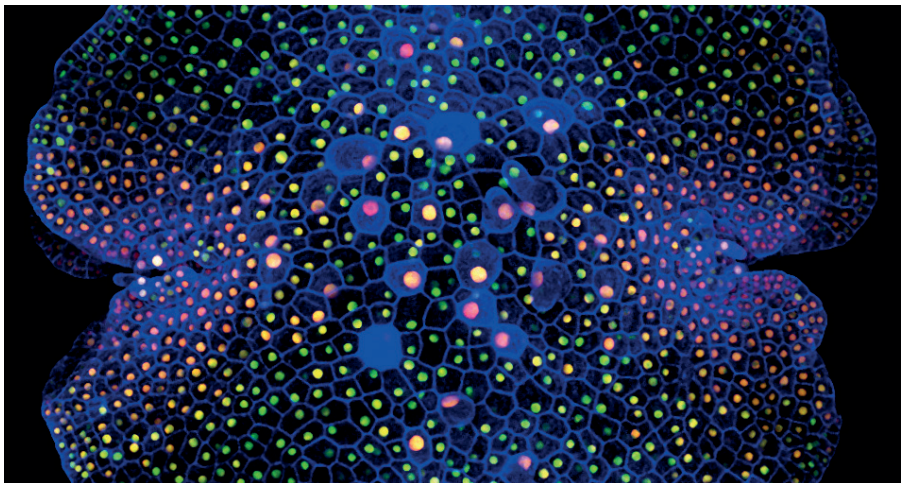
Senate House at the University of Cambridge. The OpenMTA is intended to work in existing institutional workflows but may require negotiation. Some universities such as Cambridge and Stanford provide more autonomy for researchers to share their inventions openly. Credit: Senate House by George Rex on Flickr, licensed under CC-BY-SA 2.0

NEXT STEPS

There was a clear need and desire from the majority of Open IP working group participants to provide a mechanism for exchange of DNA parts and other biomaterials that both minimises transaction costs and provides options for more open and permissive rights for the recipient. The design specifications for an open material transfer agreement were largely deemed to be appropriate. Following the workshop, the immediate actionable goals for creating and sustaining an international platform of open material exchange for plant synthetic biology were to: finalise the legal text of what we decided to call the OpenMTA, solicit further comments, implement a pilot transfer using the MTA and set up a body to provide a home for the agreement

These were successfully achieved and after extensive consultation and a period of public comments, the complete version of the OpenMTA Master Agreement is available (pg 14-15). The major challenges now lie in implementating the agreement in material transfer workflows and addressing the numerous technical, social and cultural challenges and opportunities surfaced by the group.

Further work and information-gathering will include examining how the OpenMTA fits into institutional workflows, further exploring the implications of international exchange and establishing the ancillary tools which will ensure that parts remain open and incentivise producers to contribute open parts.



OpenPlant is building a collectionof promoters to drive expression of fluorescent markers in the liverwort *Marchantia polymorpha* which will be shared with the plant synthetic biology community.
Image: Bernardo Pollak, Haseloff Lab, University of Cambridge

MAJOR CHALLENGES NOW LIE IN... ADDRESSING THE NUMEROUS TECHNICAL, SOCIAL AND CULTURAL CHALLENGES AND OPPORTUNITIES SURFACED BY THE GROUP.

OpenMTA.org as a home for the initiative

On the advice of the workshop participants, a brand and website was established to provide a home for OpenMTA versions of record (http://openmta.org). Comments can be sent via the website to the BioBricks Foundation who are the custodians of the website. Potential institutional signatories to the Master Agreement can also express interest via this mechanism.

In the future, a governance structure and community may be required to revise the legal document. Creative Commons was suggested as a model as their international community revises the set of licenses periodically via a mailing list. While these licence texts are open, the CC name and logo are trademarked to avoid misuse and maintain trust; having a logo and brand for the OpenMTA goes some way towards this goal.

Sharing DNA parts: OpenPlant and beyond

The short term goals of the OpenMTA are to create a mechanism for sharing of parts between the OpenPlant institutions in the first instance.

This key practical step was taken in 2017 with the transfer of materials between The Sainsbury Laboratory and the Earlham Institute in Norwich. In 2018, a large collection of parts for *Marchantia polymorpha* will be synthesised and can be made available under the OpenMTA following negotiation of terms and conditions with the DNA synthesis company to enable this.

Moreover, the BioBricks Foundation's FreeGenes project (https://biobricks.org/freegenes) will take requests for DNA synthesis from across the synthetic biology community and develop a resource of open parts which will be distirbuted under the OpenMTA.

THE OPEN MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF BIOLOGICAL MATERIALS

This Open Material Transfer Agreement (the "OpenMTA") and the attached Implementing Letter (the "Implementing Letter" and, together with the OpenMTA, the "Agreement") is entered into between the Provider and the Recipient (or the "Parties", as further identified in the Implementing Letter) and governs the exchange and use of the certain materials specified in this Agreement between the Parties. The provisions of this OpenMTA shall be given precedence in interpretation in the event of any conflict between this OpenMTA and the Implementing Letter.

I. DEFINITIONS:

Provider: Organization providing the Original Material. The name and address of this party will be specified in an implementing letter.

Provider Scientist: The name and address of this party will be specified in an implementing letter.

Recipient: Organization receiving the Original Material. The name and address of this party will be specified in an implementing letter.

Recipient Scientist: The name and address of this party will be specified in an implementing letter.

Original Material: The description of the Material being transferred will be specified in an implementing letter.

Material: Original Material, Progeny, and Unmodified Derivatives. The Material shall not include: (a) Modifications, or (b) other substances created by the Recipient through the use of the Material, which are not Modifications, Progeny, or Unmodified Derivatives.

Progeny: Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism.

Unmodified Derivatives: Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Material, proteins expressed by DNA/RNA supplied by Provider, or monoclonal antibodies secreted by a hybridoma cell line.

Modifications: Substances created by the Recipient which contain/incorporate the Material.

Commercial Purposes: The sale, lease, license, or other transfer of the Materials or Modifications to a for-profit organization. Commercial Purposes shall also include uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization.

II. TERMS AND CONDITIONS OF THIS AGREEMENT:

The Provider is making the Material available as a service to the research community. The Recipient may use the Material for any lawful purpose, including Commercial Purposes, in accordance with the following terms and conditions:

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Fees: The Material is provided at no cost, or with an

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No Warranties: Any Material delivered pursuant to the Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

The template of the Implementing Letter can be found at http://openmta.org

THE OPENMTA WILL BE REALLY USEFUL FOR BEING ABLE TO INTERCHANGE MATERIALS ON A VERY RAPID BASIS. WITH 3D PRINTING FILES, IN A FEW MINS YOU ARE WORKING WITH A DESIGN AND BUILDING WITH IT. THAT'S NOT THE CASE FOR BIOTECHNOLOGY.

CASE STUDIES

During 2017, several video case studies were compiled highlighting situations where the OpenMTA could catalyse collaboration through open exchange: in academia and industry, locally and internationally.

View the videos at htttp://openmta.org

Loop Assembly: sharing foundational DNA tools

Techniques for assembling multiple DNA parts can involve many components such as DNA vectors, primers and restriction enzymes that need to be obtained for each experiment. This is limiting in the context of the global South or other low-resource settings due to cost and shipping time, placing limits on the speed of research.

Fernán Federici and Bernardo Pollak (La Pontificia Universidad Católica de Chile) tackled this problem through developing Loop Assembly: a protocol for DNA assembly using only two restriction enzymes and eight vectors. Bernardo explained why, in his view, Loop materials have to be distributed the OpenMTA: ubiquitous distribution of foundational technologies makes them much more valuable than if usage was restricted.

Fernán sees the OpenMTA as a tool that facilitate collaboration between all players in the research and innovation ecosystem. He explains that particularly in a Latin American context, it is important that materials are available for companies, something which is enabled by the OpenMTA but not by existing standard agreements.

PLANT-BASED EXPRESSION IS STILL A NICHE ACTIVITY SO REDUCING BARRIERS WOULD BE A GREAT BENEFIT... PEOPLE COULD GIVE IT A GO IF THEY COULD GET HOLD OF THE MATERIALS EASILY

HyperTrans: increasing plant bioproduction

George Lomonosoff is a Project Leader at the John Innes Centre in Norwich and uses plants as bioreactors to produce vaccines and useful plant metabolites. His lab developed a system for high protein expression in plants called HyperTrans that he is keen to distribute as widely as possible around the world.

Currently, everytime someone writes to George requesting the material, the MTA is drawn up on a case by case basis. This is true even for labs on the same corridor each time they want to use the material for a different purpose. George believes that having an OpenMTA would save time and increase the number of people who are interested to use the technology by allowing them to obtain it easily with few legal barriers. This could have a multiplier effect on the number of labs using plants to produce their proteins and greatly benefit the research field.

In particular, George points out that the right to modify and reuse parts as granted under the OpenMTA is very important to encourage uses beyond those conceived of by the originating lab.

THE OPENMTA WILL REMOVE BARRIERS ALLOWING US TO GENERATE PROMISING RESEARCH AND INNOVATION AND HOPEFULLY TO CHANGE THE WORLD!

Tropic Biosciences: accelerating biotech

Tropic Biosciences is a small startup developing gene editing for tropical crops like banana and coffee, based at the John Innes Centre in Norwich. The founders explain that lots of reagents are produced in academia and published but never patented. However, when industry requests these reagents the innate response is uncertainty about rights. Arranging permissions and distribution can be complex and long-winded in their experience.

Most MTAs are restrictive and prevent commercial use or redistribution. This means that while their academic collaborators have access to the reagents, Tropic staff cannot use them for commercial collaborations. Combined with limited commerical access to biobanks and plasmid collections, this slows research and duplicates effort as startups have to reinvent or work around.

Tropic Biosciences hopes that the OpenMTA will reduce delays and transaction costs in using foundational tools and materials that are not protected by IP. They will take advantage of this to generate advances and innovation to improve global food security.

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APPENDIX 1: IDEAS GENERATED

Type	Idea / Reasons for high priority	Votes
Legal	Provide a way to give away all rights in the materials unconditionally to everyone, forever Comments: • Decision to place in public domain is a key upstream one • This point should continue to be made • Because the public domain is the only mechanism that is infinitely stable, moral and ethical. Building blocks of life	12
Legal	Set up repository agreements with institutions (like Addgene for UBMTA) Comments: • Important for uptake/dissemination of parts from academic communities • Take the work off the producers, if they are letting it go they won't want to work at it • Yes – OpenMTA should be functional without us establishing a repository	3
Legal	Trademark the OpenMTA brand/get other protection Comments: • Important for recognition, trust and acceptance • Reinforces integrity of the community – watch out for knockoffs • Institution design, version control, version evolution and communication	3
Legal	Map patent landscape Comments: • This helps people make informed decisions • A necessary step in establishing freedom to operate	2
Legal	Clarify legal status of synthetic biology post the Mayo/Myriad court cases	0
Legal	Create a viral agreement	0
Community	Community of users is important (for example, Creative Commons) Comments: • Very Important • What is created should be usable and used • This is a moral economy. It is a brutal place, not just a happy one • Very Important • Need critical mass to be near default • Need to get a culture of use	6
Community	Create information & Educational resources/FAQs on MTAs. Why do they exist? Benefits/ disadvantages of OpenMTA Comments: • Engage • OpenMTA case study, examples and different fields • Unclear to many – different benefits to different users • This point is vital for future knowledge and innovation in the communication between legal/academic/companies. • Distrust of agreements so this may assist in understanding why the MTA is required	5

Type	Idea / Reasons for high priority	Votes
Community	Create a host Institution for OpenMTA versions Comments: • Crucial for implementation of new practices • Need management • Ensure consistency, version control, ability to update as events unfold (laws change, practices change) • Agreement needs to be between legal entities – entity created for purpose • Quality and community focus	5
Community	Sexy logo and T-shirt required Comments: • Achieve popularity and used by attractiveness, make sure it's doodle-able • If it becomes a positive brand, more people will use and share • Relates to community (logo) • Distinct logo and branding, likely to increase false up as it develops	4
Community	Ambitions of OpenPlant should be to provide a clearing house and promote broader ethics Comments: • Important to keep in mind • Helps establishing community ethos • Helps articulate community aspirations and higher goals	3
Community	Create a set of Bioengineer's Rights Comments: • Could be interesting • Brilliant idea, important to bear in mind • A good model to think with and help to maintain across all biology	3
Community	PR & management of message and response required Comments: • Need clear message to the world • Prior art and standard; OpenMTA and different agreement/licensing; Guidelines for patenting and verify IP claims	2
Community	Outreach to institutions to sign on to the OpenMTA Comments: • Enables more academics to have the option of disseminating their research in ways that promote translation • You have plenty of biologists facing similar problems	2
Community	Educational materials for appropriate use of the OpenMTA Comments: • Guidance on use of OpenMTA – just part of a well thought-out announcement/launch	1
Technical	One-click licensing (don't need to wait for the institution once they are signed up to OpenMTA) Comments: • Important if OpenMTA is to be broadly useful tool and to increase ease of use for institutes • Speed and therefore frequency and success of use • Easy for users • Ease of use is paramount. Makes process symmetric for holder and recipient • Need to reduce transactional cost	4
Technical	Information about part should be linked with attribution mechanism Comments: • Important for incentivising use • Allows credit to remain regardless of human nature (i.e. not crediting in publications) • Should acknowledge accreditation. Will never be 100% it just has to be good enough.	3

Type	Idea / Reasons for high priority	Votes
Technical	Distributed public register with symbol e.g. © Comments: • Ease tech • Links well with logo idea – a simpler symbol that I can recognise • Start small, test and do first, good practices and guidelines, values and ethics	3
Technical	Predicted scale of OpenMTA? OpenPlant MTA, Open Biology MTA, Open SB MTA, OpenMTA? Comments: • Transaction cost of "material" transfer should be as low as possible • Implies no bilateral contract • Identifiers, similar to biomarkers and varieties of Open	3
Technical	Use of unambiguous identifiers e.g. OrchID, GENBANK ID Comments: • Facilitates database referencing, social links and establishing reliability • Standards	2
Technical	Connect Sequences to patent office as prior art Comments: • Very important to protect donated parts • Is important but only if there is data/use otherwise it's alerting the patent office that someone has cloned a gene	2
Technical	Create a function that allows tracking of "parts in progress" Comments: • This helps build anticipation and worthy as documentation after publication	1

More information about the OpenMTA is available at:
http://openmta.org | http://openplant.org/materials

The IP working group and OpenMTA are a collaboration between:

BioBricks FOUNDATION

OpenPlant
sharing tools for a sustainable future

OPENPLANT PARTNER INSTITUTIONS:

Earlham Institute
Decoding Living Systems

John Innes Centre

UNIVERSITY OF CAMBRIDGE

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