OPEN BIOSHARING WORKSHOPS
REPORT

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Reclone.org

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Executive Summary

The Open BioSharing Workshop Series, promoted by Beneficial Bio and Reclone.org, gathered leaders focused on developing and distributing open biological materials and resources, all committed to advancing open biosharing practices responsibly.

Open biosharing models are significantly less common than restricted models, yet several initiatives and organizations have embraced open-sharing practices. This series of workshops was organized to explore these practices, discussing collective experiences, challenges, and future plans. We took an expansive approach to openness while narrowing our approach to biological materials as we focused on replicable material rather than finite biospecimens and primary cells from patients collected in biobanks and biorepositories.

Participants were invited to consider what success looks like and how effective biosharing can be developed to support the current research and innovation ecosystem. Together, we envisioned how open biosharing could disrupt and drastically improve the bioeconomy.

CONTENTS

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Workshop participants: Anton Molina (b.next), Chonnettia Jones (Addgene), Daniela Rothschild Rodriguez (KlebPhaCol), Eric Perkins (Addgene), Franklin Nobrega (KlebPhaCol), Henry Lee (Cultivarium), Jorge Contreras (University of Utah), Katrien Claes (VIB-Center for Medical Biotechnology), Scott Pownall (Open Science Network Society), Vinoo Selvarajah (iGEM), Yan Kay Ho (Open Bioeconomy Lab, Reclone).

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About the Organizers

BENEFICIAL.BIO

Beneficial Bio is a nonprofit helping labs around the world secure reagents, tools, and services quickly, at a fair price, and with specialized local support.

Reclone.org

Reclone.org is a global community of scientists enabling equitable access to reagents to foster research, innovation, and education for the bioeconomy.

THE WHAT AND WHY OF OPEN BIOSHARING

Sharing biological materials and resources, such as DNA and cells, is essential for driving biosciences and the bioeconomy. This practice can accelerate research, especially the adoption of new techniques, by reducing redundancy and improving scientific reproducibility. Physical bioresources are often shared for convenience and cost (e.g. plasmid DNA), and sometimes sharing is the only means to obtain the material because it can not be synthesized de novo (e.g. cell lines).

As recommended by UNESCO, access to scientific knowledge should be as open as possible, but sometimes access may need to be restricted, for example, to protect human rights, confidentiality, intellectual property (IP), personal information, and traditional knowledge. Open science encourages scientists to develop tools and methods for managing data so that as much data as possible can be shared, as appropriate.[1]

In a practical example, if a researcher develops a new bioresource, such as a plasmid, they may share it with restrictions, limiting use to academia or nonprofit research. Or they can share openly, using a number of tools and approaches to minimize any legal barriers to downstream distribution, use, and adaptation. Local regulations and biosafety laws would still apply.

We consider the legal aspects of sharing open materials to be designed around five goals — access, attribution, reuse, redistribution, and non-discrimination, reflecting the principles of 'openness' set out in the Open Definition.[2,3] Openness also encompasses actions to create a commons where anyone can participate, and where interoperability between resources is maximized. In this context, the FAIR Principles also come into play: Findability, Accessibility, Interoperability, and Reuse.[4]

For example, open protocol repositories are a valuable complement to biorepositories, as they allow researchers to start from a validated workflow, troubleshoot their experience with biomaterials, and share useful tips.

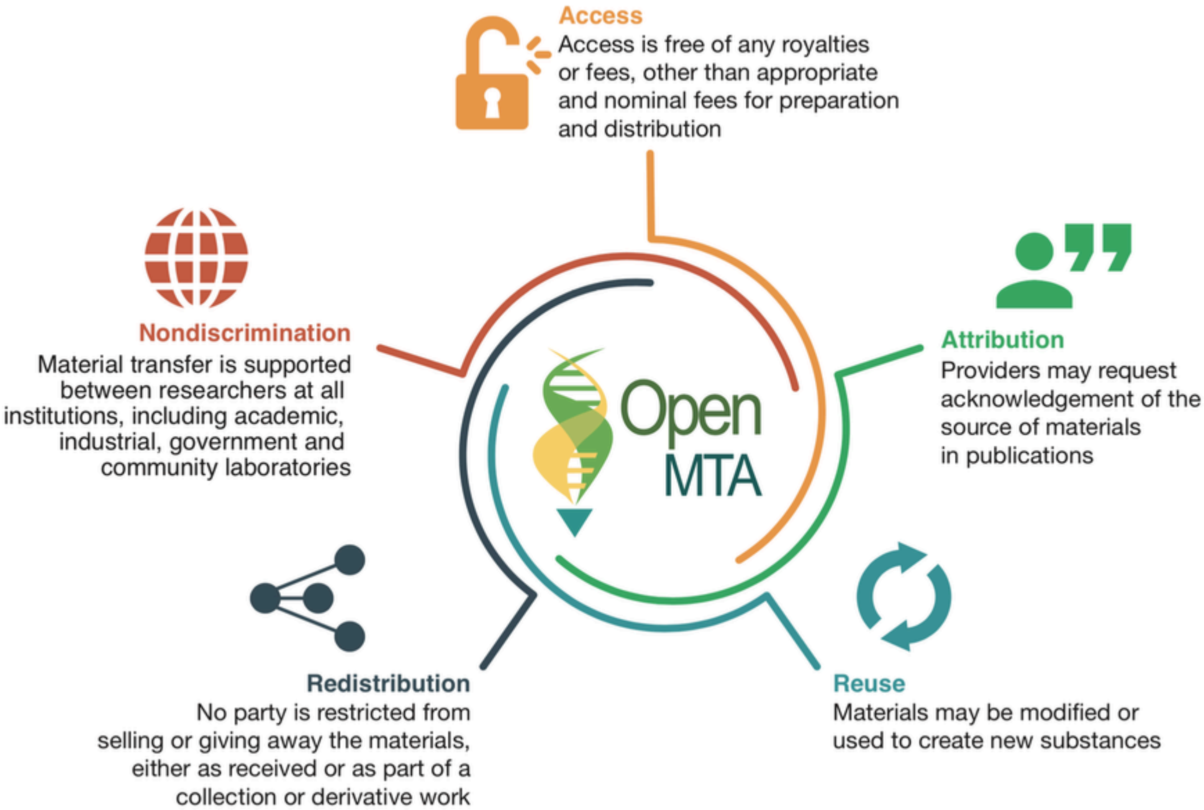

Image by Kahl, L., Molloy, J., Patron, N. et al.[2]

Open models of biosharing are significantly less common than restricted models, yet there are a number of initiatives and organizations that have adopted open-sharing practices. We organized a series of Open Biosharing Workshops to discuss their experiences, challenges, and future plans. We took an expansive approach to openness but a narrow approach to biological materials as we focused on replicable material rather than finite biospecimens and primary cells from patients collected in biobanks and biorepositories.

WORKSHOP FORMAT

The Open BioSharing Workshop Series gathered leaders working to develop and distribute open biological materials and resources, and who are committed to advancing open biosharing practices responsibly.

Our starting hypothesis is that open-sharing practices make research and innovation in biology faster and more equitable; and that openness is compatible with sharing responsibly and ethically, in line with international best practices for biosafety and biosecurity. We also started with an understanding that there are challenges in practicing open-sharing while balancing sustainability, different stakeholder expectations, and risks, which may outweigh the benefits in specific contexts.

The Workshops focused on three main goals:

- Take stock of the current state of the open-sharing of biological resources
- Consolidate lessons learned and work on potential solutions for roadblocks
- Identify ways to work collectively to overcome gaps and shared challenges

Participants were invited to consider what success looks like and how we can develop effective biosharing to support the current research and innovation ecosystem. Together, we also envisioned how open biosharing could or should disrupt and drastically improve the bioeconomy.

To facilitate the discussions, each Workshop session focused on a different aspect of the goals, and their outcomes will be presented in this report accordingly:

01 **March 13th, 2024**
Comparing Open BioSharing Practices and Experiences

02 **March 28th, 2024**
Unpacking Challenges and Barriers to Open BioSharing

03 **April 4th, 2024**
Looking Beyond the Open BioSharing Workshop Series

SESSION 1: COMPARING OPEN BIOSHARING PRACTICES AND EXPERIENCES

The Workshops convened representatives from universities, companies, and organizations developing and distributing open biological materials and resources. We acknowledged that most of the current work of the group is on DNA sharing (plasmids, DNA Toolkits), with an aim to expand to strains and cell lines.

Image generated by Mentimeter

The success and impact of open biosharing

Participants shared many experiences where sharing open biological resources has been fruitful and effective. During the pandemic, it was impressive how quickly the international community, including industry, got behind sharing completely open COVID-related tools. As a result, more stakeholders, including governments and funders, recognized the importance of open-sharing of knowledge and (bio)resources as a catalyst of innovation.

Open biosharing allows scientists to focus on testing their hypotheses, rather than to spend limited resources on procurements. This practice promotes faster and more efficient work for scientists, fostering research collaborations and re-sharing, leading to increased productivity.

Open-sharing overcomes the cost and access challenges of the traditional sharing modes for non-academic/institutional labs. It also enables research work that couldn't have happened without open biomaterials, especially for academic and startup labs in low- and middle-income countries (LMICs). Less well-resourced labs and researchers with the most difficulties in getting biological materials have been active users of open biomaterials and have had positive results in their work.

Example Cases

OpenMTA: Sharing Plasmid DNA via the Open Material Transfer Agreement (OpenMTA), which allows for commercial use. Attribution of the originator is required and all legal indemnities for the sharer are retained. Several thousand SARS-CoV-2 protein sequences for diagnostics manufacturing were shared via Addgene and Freegenes during COVID-19.[2]

Freegenes: Based out of Stanford University and the Biobricks Foundation, it also aimed to create and distribute many collections of open-source DNA sequences to support global biotechnology research, free of charge. Over 1500 collections were sent to over 250 scientists and many DNA parts were included in iGEM DNA Distributions from 2023, adding another 400 recipient labs annually.[5]

Open COVID Pledge: Encouraged organizations to make their intellectual property freely available to support efforts to combat the COVID-19 pandemic. By adopting specific and pre-established open licenses, entities were able to share their technologies and innovations. Over 500,000 patents including a number of biotechnology-related inventions were pledged by organizations including IBM, Intel and Fujitsu.[6]

Fungal Genetics Stock Center: The FGSC at Kansas State University holds over 75,000 fungal strains and considers all material in the collection to be in the held in trust for the public. It has minimal terms for users requesting strains, limited to paying the relevant fees, acknowledging the FGSC in publications and liability release The FGSC has been cited almost 150k times, demonstrating it great scientific impact.[7,8]

While success stories showcase the impact of sharing biomaterials openly, there are many challenges we need to overcome to accelerate this practice.

Roadblocks on open biosharing

During the Workshops, we collaborated to consolidate best practices and recommend potential solutions to accelerate open biosharing. The challenges identified by the participants were subsequently grouped into three overreaching areas:

Regulations, IP and MTAs	• There is no standard international definition of genetically modified microorganisms (GMOs), making shipping them internationally complex • Most standardized material transfer agreements (MTAs) are not intended for non-academic sharing, including with industry • Adapting MTAs for each requesting institution presents an increased workload and this has been experienced even with the standard Open MTA. • Lack of understanding of how open MTAs interact with patents • Time-consuming processes to find strains that don't come with MTA chains and perpetual contract restrictions, to build a completely open-access strain
DNA & Strain Distribution	• Trade-offs between sending larger collections as glycerol freezes (expensive) vs. preparing sufficient plasmid DNA (time-consuming) • Quality control, mutations and unstable plasmids • Figuring out the best way to package material and getting the correct paperwork (e.g. shipping harmonization codes) • Understanding - and overcoming - international shipping policies and customs procedures • Delays in commercial shipping, with samples getting lost in the process • Enabling redistribution of DNA and strains • Identifying repositories with higher biosafety level facilities to share certain strains
Documentation & Knowledge Repositories	• Not enough people and resources to properly curate the documentation associated with open-biomaterials • Collecting metrics of success and validation from different labs, to set it up for optimal reuse potential • Attribution and sharing credit where due, particularly across different organizational environments (academic vs industry)

Beyond these specific challenges, we also identified high-level hurdles in setting up a formalized, repeatable, faster, and scaled-up process for open biosharing. It demands a high activation energy and support, such as a sufficient number of people and resources for managing website and email, material requests, preparation and shipping, and many other logistical tasks.

Funding has also been a major roadblock encountered by organizations interested in adopting open-sharing practices. This mirrors the challenges addressed globally by many biorepositories,[9] but open-sharing generally means the removal of licensing fees and royalties as a source of income.

Building bridges with the Global South

A highlight of the discussions during Session 1 was the collective interest and current efforts to share more biomaterials in Africa, Southeast Asia, and Latin America. Researchers in the Global South need accessible resources but face significant challenges in receiving reagents, in part due to higher shipping costs and difficult customs procedures.

There is a need to better understand what types of materials are useful, which can be achieved by sharing the experimental applications, and collecting user feedback. In this sense, it is also necessary to develop training on how to prepare DNA kits and other materials once they are received, and a “train the trainers” approach is recommended. Lastly, partnering with funding agencies will be instrumental in increasing open biosharing reach in the Global South.

> Session 1 highlighted the transformative impact of open biosharing, which was particularly evident during the COVID-19 pandemic, as sharing open biological resources accelerated innovation. Despite challenges around regulatory complexities, material transfer agreements, and logistical issues, the session underscored the importance of expanding biomaterial sharing efforts.

SESSION 2: UNPACKING CHALLENGES AND BARRIERS TO OPEN BIOSHARING

The challenges identified during Session 1 were addressed in two separate breakout rooms to facilitate the discussion. Participants were invited to point out other barriers and recommend potential solutions.

Regulations, IP and MTAs

Regulation refers to the biosafety and biosecurity laws that govern the development, distribution, transport, storage and use of biological materials. When shipping these materials, compliance with local regulations is mandatory. Both the sender and receiver must adhere to all necessary legal procedures, including obtaining clearance documents and shipping permits.

Intellectual property (IP) refers to creations protected in law by, for example, patents and licenses, which enable people to earn recognition or financial benefit from what they invent.[10]

In the context of biological resources, more specifically microorganisms, the Budapest Treaty comes into place. All states party to the Treaty are obliged to recognize microorganisms deposited as a part of the patent procedure, irrespective of where the depository authority is located. Virtually, this means that a microorganism does not need to be submitted to each and every national authority to be patent protected.[11]

Material Transfer Agreement (MTA), as previously exemplified, is a contract governing the transfer of materials between two parties. It defines the rights of the provider and the recipient with respect to the materials and any derivatives.[12]

With these concepts in place, we worked on some of the current roadblocks encountered in sharing biomaterial openly.

- **Breaking perpetual MTA chains, and navigating IP and ownership for strain-sharing:** Currently, there is no public database to find materials deposited via the Budapest Treaty, with requestors instead having to find the specific patent and then go to its repository. Centralizing efforts and resources would be beneficial, such as creating a forum for developing a better mechanism, that could include leveraging AI (artificial intelligence) tools to data mine patents for relevant details.

- **Understanding how open MTAs interact with patents:** Similarly to navigating IP, there is a need for a shared conversation with experts who understand patent law. Also, compiling common MTA and IP questions into a FAQ (Frequently Asked Questions) page could be useful.

- **Mapping the adoption of open MTAs across different sectors:** Evaluating whether this approach has improved sharing practices is essential, with user stories showcasing different ways to share materials. There is a need to teach how open MTAs work virtually and create a database of examples and agreements that could be useful to increase their adoption.

DNA & Strain Distribution

While the cost of DNA synthesis has significantly reduced over the years, re-synthesizing DNA at scale perfectly is still cost-prohibitive. The distribution of DNA collections helps mitigate these problems. A number of options with specific trade-offs and important points for consideration were identified through discussion:

- **Sending larger collections as glycerol freezes (expensive) vs. preparing sufficient plasmid DNA (time-consuming):** For larger collections, automation is essential. It is also necessary to ensure effective transformation by using competent cells and providing positive controls to minimize user errors. In this sense, knowledge sharing, with tested protocols and collaborative troubleshooting becomes increasingly important. Collaboration with established companies or non-profit organizations such as Addgene can help refine workflows by integrating best practices, emphasizing quality control and quality assurance.

- **Collecting metrics of success and validation from different labs, to set the materials up for optimal reuse potential:** To streamline documentation of issues and feedback, a lightweight and automated system is essential. This could involve using AI chatbots or digital work instructions to ensure compliance with a protocol checklist, integrating QR codes for tracking material samples, and leveraging platforms like GitHub for structured issue reporting. Implementing practical and accessible procedures will help standardize the process of distributing and using open DNA and strains, while engaging academia, industry, and community labs will enhance practical contributions to ongoing development of open collections, and to resource sharing.

- **Enabling redistribution of DNA and strains:** Centralized distribution ensures consistency and control but can be less flexible and slower to adapt. Decentralized redistribution hubs offer increased accessibility and innovation but may pose biosecurity challenges for some materials, and require robust standardization for terminology, tools, MTAs, and best practices. Proper credit and citation must be emphasized, and mechanisms for downstream sharing should be encouraged. Repositories should incentivize redepositing improved or adapted materials to enhance communal resources. Lowering barriers to entry for those outside academia is crucial, as open resources should foster adaptation and innovation across sectors.

There are other gaps and shared challenges that were not addressed during the limited timeframe of our Workshop Series.

Session 2 focused on identifying and addressing barriers to open biosharing, such as regulatory, IP, and MTA challenges, and the logistics of DNA and strain distribution. Participants emphasized the need for centralized resources, automation, and improved collaboration to streamline processes and enhance the adoption and impact of open biosharing practices.

SESSION 3: LOOKING BEYOND THE OPEN BIOSHARING WORKSHOP SERIES

To continue the work initiated by the Workshops, we focused our Session 3 on looking beyond, outlining the next steps for our collective efforts.

Growing a sustainable community and envisioning a roadmap

Together, we plan to solidify a community of practice for open biosharing with a distinct presence and identity, and continue working together to develop open biosharing across different sectors. We have identified important next steps and action points to prioritize:

01 Share current resources and best practices for open-sharing of biomaterials, drawing on the extensive and hard-earned knowledge of the workshop participants.

02 Develop success stories, exemplifying the potential of open biosharing, including for pandemic preparedness, research in LMICs, education and other areas where participants have concrete case studies.

03 Create a mechanism to identify material needs and applications, and a framework to recognize efforts and contributions to incentivize further adoption and redistribution.

Most importantly, we aim to collectively enable the field to scale up, engaging with publishers and funders to raise more visibility and awareness; establishing partnerships that can support open biosharing and, as a result, incentivize more groups, organizations and initiatives to participate.

Open biosharing encompasses different practitioners, who we hope will join our community. We invite researchers, industry professionals, publishers, and policy-makers to join along with open-source hardware and software developers.

As we grow our community, we plan to implement more active communication channels and invite ideas and suggestions on platforms to develop our work. For now, we have started a mailing list, where others are welcome to join - reach out to coordination@reclone.org to know more!

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