Open Science Policy for Developing Medicines through Open Science program

Background

Developing Medicines through Open Science (DMOS) is a program from Conscience that funds and supports drug discovery and development in areas of market failure. DMOS only supports projects committed to open science principles and practices, which create openly available outputs that can be used and replicated by future researchers. This policy explains Conscience's open science requirements to ensure maximum disclosure of useful information without overburdening project managers.

Overall Policy

The chemical structure of potentially therapeutic molecules created or developed through an DMOS supported project (**"Project Molecules"**) as well as the data generated to support claims of therapeutic potential (**"Project Data"**) must be shared publicly and without restrictions on use as soon as practicable but no later than the end of the Conscience funding term. Projects must also publicly share information concerning all methods and materials used in sufficient detail so as to enable others to reproduce results and replicate experiments.

Policy Statements

Open Therapeutics

All Project Molecules must be shared publicly, free of any patent-based restrictions that would prevent others from using that molecule for any purpose.

Required Practices

- Conscience will work with successful applicants to create a reporting schedule. The reporting schedule will include time-based and milestone-based reporting of results and clearly state points when open sharing of Project Molecules is required.
- Information about Project Molecules should be shared in an appropriate repository or digital chemical library where one exists.
- Project Molecules should be shared using open formats and standards and according to the FAIR (Findable, Accessible, Interoperable, Reusable) principles.
- Requests by other researchers for access to project molecules must be honored within a reasonable timeframe. Honoring such requests can be accomplished by providing details concerning where molecules can be commercially procured or, in the case of de novo molecules, details concerning the synthesis steps and experimental protocols for creating them.

Open Data

Project Data - meaning data supporting results about the therapeutic potential of Project Molecules - must be shared publicly, free of any intellectual property or contractual restrictions that would prevent others from using that data other than restrictions based on submissions to a health regulatory agency.

Required Practices

- Conscience will work with successful applicants to create a reporting schedule. The reporting schedule will include time-based and milestone-based reporting of results and clearly state points when open sharing of Project Data is required.
- How data will be generated, stored, and shared is to be outlined in a Data Management and Sharing Plan created at the beginning of the project.
- When creating your Data Management and Sharing Plan and working with Conscience to create a reporting schedule, you must carefully consider at what level of processing Project Data should be shared. In some cases this may be raw data, while in others it may be data that has been processed to some level. *The overriding principle is that the data should be sufficient to enable others to reproduce, verify, and build upon reported results in a scientifically robust way.*
- Project Data should be shared in an appropriate domain specific or general repository and in such a way as to waive any intellectual property rights in that data to the extent allowed by law. Waiving such rights can be accomplished by sharing under a Creative Commons Public Domain Dedication (CC0) or equivalently permissive tool.
- Where such standards and formats exist, Project Data should be shared using open, machine-readable formats and common scientific standards.
- Project Data should be shared according to the FAIR (Findable, Accessible, Interoperable, Reusable) principles.

Sharing Methods and Materials

For the purpose of successfully completing a DMOS project, applicants may either (1) use methods or materials that are patented or otherwise restricted by IP or (2) create new methods or materials that could be subject to new patents or other IP.

Proprietary or otherwise restricted methods and materials created before a DMOS project or created outside of the scope of the project–including computational methods (e.g., software) and physical methods and materials (e.g., assays and reagents)--may be used in developing or generating Project Molecules and Project Data. If such proprietary methods or materials are used, they must be described in sufficient detail to enable others to replicate any results and the description must be publicly shared.

Any new methods or materials created for the purpose of completing a DMOS project must be described in sufficient detail to enable others to replicate any results, the description must be publicly shared, and be free of any intellectual property or contractual restrictions that would prevent others from using that method or material.

Required Practices

- Conscience will work with successful applicants to create a reporting schedule. The reporting schedule will include expectations as to when and how information about materials and methods must be publicly shared.
- Where compatible with high standards of research practice, projects should use open source software. The ubiquity of software in research - including searching and summarizing literature, running equipment, acquiring data, storing data, processing data, and reporting results - means that it is likely that it will not be possible to find appropriate open source software across all uses. Nonetheless, efforts must be made to identify and use such software.
- Where compatible with high standards of research practice, projects should use open methods (e.g., kits, assays, and experimental procedures that are not subject to intellectual property rights). Where this is not

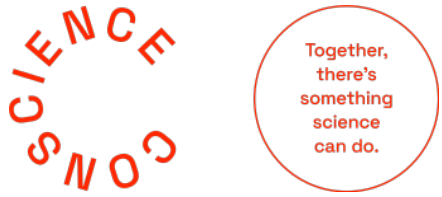
possible, the methods used must be described in sufficient detail to enable others to replicate experiments and that description shared publicly. Ideally, such methods are to be shared via an appropriate methods-sharing platform (e.g., protocols.io) as well as via a preprint and/or an Open Access publication.

- Where compatible with high standards of research practice, projects should use open materials and reagents (e.g., probes, cell lines, plasmids, antibodies). Where this is not possible, the materials used must be described in sufficient detail to enable others to replicate experiments and that description shared publicly.

Frequently asked questions

- **What if I already have a patent on the molecule I want to develop under a DMOS project?**
    - You can still apply, though keep in mind that the project as a whole must comply with this policy. This requirement means that the Project Molecule - which may or may not be related to the originally patented molecule - must be useable by others without restriction. If using the Project Molecule is likely to infringe the initial patent, you will be required to license the patent openly, world-wide, and without cost.

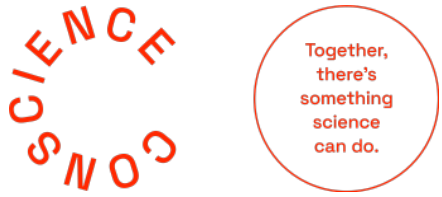
- **What if I develop new software, materials, or methods while the project is ongoing that is outside the scope of the funded project? Can I have IP rights in those?**
    - Yes. The public sharing and IP-free requirements of this policy only extend to the Project Molecules, Project Data, and any methods or materials created for the purpose of completing a DMOS project. If



you develop new materials or methods for a purpose other than the completion of a DMOS project you may protect them as you wish. However, complying with this policy means that if those new methods or materials are used in the DMOS project and are needed to replicate results, full descriptions must be shared publicly in accordance with the reporting schedule, which may have implications on efforts to obtain or enforce intellectual property rights.

- DMOS projects are supported by funds from Innovation, Science, and Economic Development (Canada). Under Conscience's agreement with ISED there are restrictions concerning how IP can be sold and licenced, including a requirement to obtain approval before selling it outside of Canada for 5 years and around granting exclusive licenses. Any IP created to complete a project that is outside the scope of this policy will be subject to those restrictions.
- Failure to comply with this policy may result in a requirement to return all project funding to Conscience.
- Finally, the secrecy required to obtain a patent may prevent you from sharing information that could lead to useful outside input and hinder collaboration.

- **After the end of the project, can I patent further advancements on molecules developed during an DMOS supported project?**
  - Yes. Complying with this policy means that the Project Molecules and Project Data must be free from patent or other IP restrictions and the requirement for public disclosure of the Project Molecules will prevent anyone getting a patent on it. However, you or anyone else is fully free to patent later advances or alterations to Project Molecules. Whether such advances qualify for patent protection, or



whether such protection is advisable, is a business decision you must make. Obtaining such a patent may, however, prevent you from obtaining further funds under the DMOS program (see first FAQ bullet).

- **The policy on Project Data mentions "restrictions based on submissions to a health regulatory agency". What does that mean?**
    - Health regulatory agencies (e.g., Health Canada in Canada, the FDA in the USA, EMA in Europe) are responsible for approving new medicines based on evidence submitted to them about safety and efficacy. These agencies often have rules about when later applicants can rely on this data. For example, in both Canada and the USA, there is a period after a new medicine has been approved where others cannot use the safety and efficacy data from clinical trials to prove equivalence in order to gain approval on a competing product. This is called Data Exclusivity, which is a type of "regulatory exclusivity". Market Exclusivity is another important type of regulatory exclusivity. This policy is written so as to preserve those regulatory exclusivities, which can be thought of as a more targeted and tailored, and consistent with open sharing, form of IP when compared to a patent.

Conscience Can Help!

If you have any questions concerning this policy please contact Conscience for further information. We can assist you in identifying appropriate open science strategies and resources, both when drafting a proposal for an RFP and during the course of a funded project.