

Charter of Open Pharma

Article 1. Mission and objectives

To drive improvements in healthcare, the dissemination of pharmaceutical industry research results should be faster, more transparent, more accessible and more efficient than at present. Open Pharma aims to improve the publications model by connecting pharma with contemporary innovations in publishing. Open Pharma is a collaboration of forward-thinking individuals representing a number of important stakeholder groups: the pharmaceutical industry, publishers, patients, academics, regulators, editors, non-pharmaceutical funders and societies. Our aims are to identify emerging trends in scholarly publishing, discuss their implications for pharma and explore how they might be used to improve the way in which industry-sponsored research is disseminated. We hope that, through this collaboration, we can help to drive much-needed innovation. Our work drives towards the broad goal of improving how biomedical research is communicated, focusing on four main objectives.

- **Transparency:** to increase the transparency of research disclosure and the publication process by investigating ways to maximize openness while safeguarding scientific rigour and data integrity.
- **Accessibility:** to make articles more widely available to read and reuse by everyone, to reduce or remove the paywalls that currently restrict access, and to encourage accessible communication, such as plain language summaries, for all peer-reviewed publications.
- **Speed:** to reduce the time between submission and publication by identifying innovative models of review and production suitable for publishing industry-sponsored research.
- **Efficiency:** to reduce the administrative burden of publishing articles by contributing to the development and uptake of systems for identification, formatting, submission and compliance processes that work across journals.

Article 2. Participants

Participation in Open Pharma is by invitation only to eligible companies, organizations and individuals who are stakeholders in medical publishing. Open Pharma is funded by voluntary contributions, and both financial and non-financial supporters can influence the direction of the project. Individuals or organizations who are debarred, suspended, excluded or otherwise declared ineligible from any state, federal, national or international agency or programme will not be able to participate in Open Pharma. The final decisions on project direction and participation remain with the Open Pharma Steering Committee.

Section 1. Secretariat

Open Pharma™ is a trademark and project of Oxford PharmaGenesis, Tubney Warren Barn, Tubney, Oxford, OX13 5QJ, UK, a limited company incorporated under the laws of England and Wales.

Open Pharma is not a profit-seeking project, and Oxford PharmaGenesis contributes much of the time spent by its staff on Open Pharma at no cost to the project or its other corporate supporters. As part of the work needed to run Open Pharma, Oxford PharmaGenesis provides a secretariat service, acting with direction from the Steering Committee and Chair, including structuring, facilitating and reporting on discussions, and developing materials as needed.

Section 2. Non-funding advisers

Advisers are invited by Oxford PharmaGenesis to take part in specific activities, such as presenting at a workstream meeting, or to join a more general list of interested parties who will be contacted for their interest in involvement in Open Pharma objectives, discussions, materials and events. Participants may ask to join or to be removed from specific activities or the overall list at any point. New advisers may be invited to join the project by the secretariat or by the Steering Committee on request or as judged by Oxford PharmaGenesis to be beneficial to the aims of the project.

Section 3. Members and Supporters

Participants are invited to contribute funding to Open Pharma, in the form of grant request proposals from Oxford PharmaGenesis. Oxford PharmaGenesis is actively seeking additional financial supporters from the pharma, publishing and funding sectors. Current financial supporters are also encouraged to explore suitable organizations and encourage them to support the project. Prospective financial supporters should be proposed to the Steering Committee before they provide funding and become part of the project. Once accepted by the Steering Committee, and following commitment of funds, new financial supporters will be invited to join the Steering Committee. Any Steering Committee member may resign at any time upon written notice to the Steering Committee. Funds committed or due will not be refunded. Financial supporters will be able to contribute to the project at two levels: Members and Supporters.

Members will provide a contribution of GBP30 000 per annum. This rate, correct as of 15 January 2020, may be changed at the discretion of the Steering Committee. Membership will confer the right to appoint representatives to the Steering Committee and provide input on the direction and priorities of Open Pharma for the period of 1 year. Members will be responsible for making important decisions, will have the opportunity to work with the Open Pharma team, will be able to co-author research and will be guaranteed a seat at the table with non-industry stakeholders for Open Pharma roundtable meetings.

Supporters will provide a contribution to the value of GBP10 000 per annum. This rate, correct as of 15 January 2020, may be changed at the discretion of the Steering Committee. Supporters will be involved in Open Pharma email correspondence and will be invited to provide their insight and suggestions for Open Pharma activities. These insights and suggestions will then be presented to members to inform their decision-making. Supporters may attend Open Pharma roundtable meetings when places are available and will be kept updated when any new resources are developed.

Commitments of financial contributions from participants and non-participating funding bodies are measures of perceived value of the project, and if the budget obtained is lower than the amount required to complete the proposed projects, Oxford PharmaGenesis acting in consultation with the Steering Committee reserves the right to either adjust the remit of the project or bring it to a close.

Section 4. Funding administration

Funds are sought by proposal, outlining specific activities and budgets expected for the whole Open Pharma project in a specific funding cycle time, and asking each supporter to pay a proportion of the total. To date, funding cycles have been by calendar year. Oxford PharmaGenesis will report to the Steering Committee and to individual financial supporters on funds obtained and used, either at the end of Open Pharma funding cycles or at the request of the financial supporter.

Funding can be provided as fee-for-service, direct grant, unrestricted educational grant or collaboration and any other mechanisms prospective supporters or members see fit. Members are encouraged to elect a representative to serve on the Steering Committee but are not mandated to do so.

By default, funding is pooled into one budget pot, covering research activities, publications and educational activities agreed by the Steering Committee. Oxford PharmaGenesis will remain free to vary the degree of non-funded support that it provides to Open Pharma. When Members and Supporters propose additional activities that fall outside the agreed activities in a budget period, or when agreed activities are no longer suitable, Oxford PharmaGenesis may change planned activities, in consultation with the Steering Committee and Chair. Participants and financial supporters retain the right to contract with Oxford PharmaGenesis for support with work on Open Pharma topics with a specific focus on their company. These activities would be handled separately from the Open Pharma project but may involve members of the Open Pharma team at Oxford PharmaGenesis. Non-commercial organizations willing to offer support to the project may negotiate support in kind on an ad hoc basis.

Section 5. Proxies

Participants are welcome to include additional people from their team in Open Pharma. For meetings or conversations during which decisions are being made on future activities, such as at a Steering Committee meeting, ideally, each member company would have one representative. Participants who are unable to attend are encouraged to explicitly identify the degree to which a proxy can speak on their behalf. This is especially the case for Members. For meetings at which space is limited, organizations may be asked to send only one participant.

Section 6. Termination

Any participant may withdraw from Open Pharma at any time, with or without cause, by contacting Oxford PharmaGenesis. The effective date of termination will be the date stated in the notice of termination. There will be no refund of payments made or due.

Participants may be removed if they break the terms of this charter; in particular, if they cease to meet the eligibility requirements, violate the policies on information sharing or if they become debarred, excluded or rendered ineligible from any state, federal, national or international agency or programme.

Oxford PharmaGenesis reserves the right at any time, in consultation with the Steering Committee, to adjust the scope of the Open Pharma project, close it or transfer it to another organization to act as secretariat.

Article 3. Governance.

Section 1. Steering Committee

A Steering Committee will provide direction to Oxford PharmaGenesis on the affairs of Open Pharma. The Steering Committee will comprise one or two representatives from each funding Member, including Oxford PharmaGenesis. It is not mandatory for a Member to be in the Steering Committee; however, it should be recognized that this is the primary decision-making forum for the project. Once admitted, seat holders on the Steering Committee will remain on the committee for a period of 1 year, after which they may be reconfirmed or leave the committee. The Chair is not a standing member of the Steering Committee but may be invited to meetings at the discretion of the Members.

The Steering Committee will meet at least once per year, and additionally as needed, either face-to-face or virtually. Topics may also be discussed by email or other means of communication as needed. Oxford PharmaGenesis will compile an agenda with proposals and issues to discuss with the Steering Committee; members, supporters and advisers are all welcome to submit agenda items. The Steering

Committee will be facilitated by Oxford PharmaGenesis and will operate by consensus. Major policy statements and other significant decisions may be put to a vote. Steering Committee members may abstain from a vote, if desired. A simple majority of the entire Steering Committee will constitute a quorum for decisions. Non-vote items are not binding and are advisory direction only for actions for Oxford PharmaGenesis and other participants. Discussions within the Steering Committee are confidential unless agreed otherwise. Decisions made by the Steering Committee will be reported to the Supporters and other participants as relevant.

Section 2. Chair

The founding Chair of Open Pharma is Dr Richard Smith, acting as a paid consultant to Oxford PharmaGenesis. The Chair is paid for their time at a fair market rate, and reasonable expenses as agreed are necessary for the project. The role of the Chair is to initiate contact, facilitate meetings, review materials and be involved in the direction of Open Pharma. In the case that the serving Chair wishes to resign their post, a replacement will be agreed and invited by the Steering Committee following a vote. Candidates for Chair will be shortlisted by Oxford PharmaGenesis, and suggestions from all members, supporters and participants will be encouraged to inform this shortlist.

Section 3. Workstreams

As directed by the Steering Committee, Oxford PharmaGenesis may convene small groups of participants of Open Pharma as workstreams, to investigate specific topics and develop materials. Activities of the workstreams report to the Steering Committee.

Article 4. Communications

Section 1. Public communications

Views given by Open Pharma are those of Open Pharma as an organization, not necessarily those of the individuals within it or the companies they represent. Any views associated with named individuals, companies or organizations will only be shared with their explicit consent. Obtaining authorization via the correct internal company or organizational processes is the responsibility of participants, not of Open Pharma. Open Pharma excludes liability in full for failure by any participant to secure the necessary consents.

Funding companies will be named on the Open Pharma website and other materials as appropriate, for transparency. Companies are responsible for obtaining all appropriate licences and consents for use of their logos and intellectual property in this context. Logos will not be associated with specific statements or used in a promotional capacity. Funding amounts will not be specified.

Section 2. Notices

Participants will be notified of developments relevant to them by email. Personal contact details are retained, for this purpose, on a secure server and are not accessible to anyone outside the project team. Participants can opt in or out of communications at any time. Participants are encouraged to discuss relevant topics with each other through email. However, owing to the long and growing list of participants and different groups involved in various activities, participants are not encouraged to use the full set of email addresses for Open Pharma as a basis for starting new conversations, unless the topic is directly relevant to the whole group.

Section 3. Meetings

Virtual and face-to-face meetings are held as needed by the project or called by participants. When participants are not available to take part, they are encouraged to provide their input by email, telephone or other methods in advance.

Section 4. Records

Internal Open Pharma meetings will be minuted under an adaptation of the Chatham House Rule: participants are free to use the information received, and verbatim quotes recorded, but neither the identity nor the affiliation of the speaker will be revealed. However, identities of participants at meetings will be recorded for the internal minutes. Minutes of specific meetings may be developed for public posting, and the identities of participants will be reported upon the approval of those named. Data and materials provided by participants may be shared freely within the group; however, unless permission has been explicitly given to do so, they should not be distributed more broadly.

Section 5. Social media

The @_OpenPharma Twitter account is operated by members of the Open Pharma team at Oxford PharmaGenesis, in compliance with the company's social media policy. No information on specific drugs will be posted or reposted. All content will be checked for editorial consistency and reputational impact for participants in Open Pharma before posting; however, Oxford PharmaGenesis does not accept liability for any damage that may occur, real or perceived. Once posted on @_Open Pharma, content may be shared by individuals and organizations on Twitter and other social media platforms, such as LinkedIn and Facebook, without any acceptance of liability by Oxford PharmaGenesis. Retweets by the Open Pharma account should not be considered endorsements.

Section 6. Website

Oxford PharmaGenesis develops and maintains a public website for Open Pharma (<https://openpharma.blog/>). As of 2019, the website is hosted by WordPress under a WordPress business licence. Opinions on the website, as for all Open Pharma communications, reflect only the opinions of contributors rather than those of their organizations, unless explicitly stated.

Article 5. Amendment

This Charter may be altered, amended or repealed by the Open Pharma members, at any time.

Adopted: 27 September 2019

Updated: 15 January 2020

Appendix 1. Members and Supporters 2020

Section 1. Members for 2020

- Galápagos NV
- Gilead Sciences
- GlaxoSmithKline (GSK), represented by the GSK Vaccines division
- Novo Nordisk
- Takeda (formerly Shire)

Section 2. Supporters for 2020

- Alexion
- AstraZeneca
- Novartis
- Pfizer
- Roche
- UCB
- Wiley

Section 3. Acknowledgement for financial support in previous years

Open Pharma is also grateful to previous contributors:

- Wellcome Trust