



techMATCH - Champion intraocular therapy drug delivery systems

How would you propose to progress intraocular drug delivery systems for the posterior segment that ensure sustained release over at least three months for diverse therapeutic modalities?

Answers to this <u>question</u> including a proposal for collaboration can only be considered if they arrive no later than July 9, 2024, 11:59 pm PST.

What is the context of the problem that we would like to solve?

The field of intraocular pharmacotherapy, particularly for posterior segment eye diseases, faces a daunting challenge: the development of efficient, long-lasting drug delivery systems. Intravitreal drug delivery presents significant challenges due to the eye's unique structure including the close proximity to the sensitive retinal tissue.

Current main treatment regimens often require frequent administrations, leading to patient discomfort and increased risk of complications. These issues not only diminish the effectiveness of treatments but also place a substantial burden on both patients and healthcare systems. There is a pressing need for innovative solutions that can reliably deliver drugs to the posterior segment of the eye over extended periods. With this opnMe call, we invite scientists to explore and progress drug delivery systems for the application into the eye, with a particular focus on implantable/injectable formulation approaches and applicators. The goal is to create systems capable of maintaining therapeutic drug levels for at least three months, preferably longer, thereby reducing the frequency of drug administration. Such advancements would represent a significant breakthrough in ocular medicine, enhancing patient compliance, reducing the risks associated with frequent interventions, and ultimately improving the efficacy of treatments for various ocular diseases.

The successful development of these technologies would not only set new standards in ocular drug delivery but also pave the way for more effective, patient-friendly treatments. This initiative aims to catalyze innovation in this critical area of ocular health, with the ultimate objective of significantly improving patient outcomes and advancing the field of ocular pharmacotherapy.

In summary, we invite you to share your ideas on improving intraocular drug delivery for the posterior segment, ensuring sustained drug release for at least three months, and covering diverse therapeutic modalities ranging from low molecular weight compounds to complex molecules. Your proposal could address the unmet needs of patients with ocular diseases and significantly impact the field of ophthalmology.

What potential solutions could be in scope?

We welcome proposals encompassing a broad spectrum of technologies, including but not limited to, implants (with a preference for biodegradable materials), micro- and nano-scale drug carriers, smart release systems responsive to environmental triggers, and innovative device with no specific material restrictions and applicator designs.

With to implant-based drug delivery systems, these could cover a wide range of technological solutions from biodegradable implants, microfabricated drug reservoirs, nanoparticle-embedded implants, osmotic pump implants as well as smart implants with sensing capabilities.

Proposals should prioritize safety, patient comfort, and adherence, alongside the technical feasibility of delivering a diverse range of therapeutic agents from low molecular weight compounds to complex molecules.

We prefer proposals focusing on reaching the next decision point or milestone towards clinical readiness.

What potential solutions would be out of scope?

The following will be considered out of scope:

- Cell and Gene therapy-based solutions
- Delivery approaches via oral administration

What benefits do we offer to you in exchange for having submitted a solution?

This opnMe call represents a unique opportunity to showcase your expertise and skills in the challenging field of (intra-)ocular drug delivery.

By participating, you have the chance to collaborate with Boehringer Ingelheim, represented by a diverse team of experts in drug delivery, pharmacology, and biomedical engineering, to gaining valuable insights, and experience.

You would be able to leverage cutting-edge technology of the relevant departments within the company. By providing access to state-of-the-art technology and facilities, selected winners of this call will be able to develop and test their ideas in a highly advanced environment of a leading company in the field of retinopathies.

In addition, the program offers global exposure and the opportunity to network with leading professionals and researchers in the field, enhancing career prospects and professional growth. As part of this call for novel approaches, participants will have the opportunity to secure intellectual property rights for their innovations, with a potential for commercialization and partnership with a leading pharmaceutical company.

Winning proposals should expect appropriate funding that will help them to bring their conceptual idea to the next level whereby we assume that increasing complexity and maturity of the proposed solution may require different budget terms that would be negotiated with the selected partners in good faith. Depending on the status of the project and applicability, we also offer a range of possibilities to support the winner besides funding. Examples are engineering capabilities for design reviews, including a strong connection to patient insights, prototyping or pharmacokinetics studies with a range of relevant molecules. We prefer to receive proposals focused on a timeframe of 1-2 years to reach the next decision point or milestone towards clinical readiness. However, we also invite concepts at an earlier stage with a longer time horizon if a potential successful implementation has breakthrough potential to change the ocular drug delivery paradigm.

Upon a successful outcome, we foresee to engage in a long-term collaboration with the selected winner with the ultimate goal of delivering Boehringer Ingelheim drugs to patients using this technology. We hope that this longer-term partnership will help to build up trust and commitment on either side of the partnership. This is a collaborative approach, where we work together to find solutions that benefit everyone involved.

Particular emphasis will be made on finding mutually agreeable solutions concerning each partner's rights & obligations (including intellectual property rights). Furthermore, winners

will be encouraged to publish their findings following the collaboration agreement, which will be negotiated in good faith. We hope that this represents a great opportunity for your innovative ideas and solutions to gain recognition in the scientific community.

For some winners, it may be beneficial to announce their partnership with Boehringer Ingelheim. Depending on the conditions of the agreement and mutual needs, we would be open for such an arrangement.

What are the key success criteria on which we base our selection for the best answer?

- Innovation and Originality: The proposed solution should demonstrate a high level of innovation and originality, offering a novel approach to ocular drug delivery. It should aim to be implemented clinically within 1-2 years and address the in-scope and out-of-scope criteria of this call. However, we also invite concepts at an earlier stage with a longer time horizon if a potential successful implementation has breakthrough potential to shift the ocular drug delivery paradigm.
- In particular, the successful solutions will focus on a clear hypothesis and how anticipated hurdles in conjunction of the proposed novel approach will be overcome. In particular, the following aspects should be addressed:
 - Effectiveness in Drug Delivery: The ability to effectively deliver drugs to the targeted posterior area of the eye
 - Safety and Patient Compliance: Solutions must prioritize patient safety and comfort, with a design that promotes patient compliance and minimizes risk
 - Feasibility and Scalability: The proposed system should be technically feasible and scalable for potential clinical application including suitable injector/applier and mass production
 - Sustainability and Environmental Impact: Consideration of the environmental impact of the drug delivery system, including sustainability in manufacturing and disposal
 - Regulatory Compliance: Adherence to regulatory standards and guidelines for medical devices and drug delivery systems
- In addition, a successful proposal will have a clear outline of the required funding budget and a time plan where it should be assumed that Boehringer Ingelheim

- would fund the next step towards proof-of-concept of the proposed novel technological solution for ocular drug delivery
- If required, the successful proposal will be well structured in milestones and planned with key decision points (clear go/no-go criteria)
- A mitigation plan is included to overcome the anticipated hurdles that also includes a contingency plan in case one approach may not lead to the desired outcome
- An ideal solution will discuss how the acceptance of the proposed sustainable drug delivery solution and potentially required behavior changes can be increased for relevant stakeholders including physicians, regulatory bodies, payers, and in particular patients
- Indication on cost-of-goods, including projected cost-breakdown, scalability and manufacturability to high production volumes is a plus
- Information regarding intellectual property / third party infringement used in the context of the submission
- Successful proposals will be supported by scientific teams who bring in a proven track record in the required field of expertise
- The access to relevant infrastructure to implement the proposed solution is a prerequisite of a collaboration with Boehringer Ingelheim

What information should be included in your answer submission?

Please use our answer submission template to provide a 2–3 page <u>non-confidential</u> proposal (available for download on the following <u>site</u>).

If confidential data exists that would strengthen the proposal, please indicate that information is available to share under a Confidential Disclosure Agreement (CDA). If we find the non-confidential concept proposal sufficiently interesting, we will execute a CDA for confidential discussions.

Anticipated Project Phases or Project Plan

- Phase 1 Please complete your submission by **July 9, 2024, 11:59 pm PST at** the very latest.
- Phase 2 Our review of all proposals will be completed by mid-September 2024 and scientists will be informed after that.
- Phase 3 Start of discussions for the collaboration agreement in Q4/2024.

Submitting a collaboration proposal

- Check the outline of the techMATCH <u>"Champion intraocular therapy drug delivery systems"</u> question on opnMe.
- Alternatively, you may click the "Get Submission Template" banner to access the material transfer template.
- Follow the instructions to upload your submission document (requires login or registration).
- The upload allows you to attach additional application files if desired.
- You will be able to access your final submitted collaboration proposal in your personal dashboard and follow its review status.
- Please also visit the <u>FAQ</u> section on opnMe.com to learn more about our techMATCH program.

References

- Chen J., Zhuo X., Zhu Y., Zhuo Y. Multidisciplinary Approaches in the Treatment of Retinal Degenerative Diseases: A Review. *Adv. Therap.* 2024, 7, 2300162. DOI:10.1002/adtp.202300162.
- 2. Gabai A., Zeppieri M., Finocchio L., Salati, C. Innovative Strategies for Drug Delivery to the Ocular Posterior Segment. *Pharmaceutics* **2023**, 15(7):1862. DOI:10.3390/pharmaceutics15071862, PubMed.
- 3. Kim H. M., Woo S. J. Ocular Drug Delivery to the Retina: Current Innovations and Future Perspectives. *Pharmaceutics* **2021**, 13(1):108. DOI:10.3390/pharmaceutics13010108, PubMed.
- 4. Ahmed S., Amin M. M., Sayed S. Ocular Drug Delivery: a Comprehensive Review. *AAPS PharmSciTech.* **2023**, 24(2):66. <u>DOI:10.1208/s12249-023-02516-9</u>, <u>PubMed</u>.