opn2EXPERTS - Progress sustainable drug delivery device technologies

How would you propose to overcome technological, conceptual, and economic hurdles associated with the development of a next generation drug delivery device with a more favorable ecological footprint?

Answers to this question including a proposal for collaboration can only be considered if they arrive no later than March 6, 2024, 11:59 pm PST.

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

Recently, peptide-based medicines emerged as a new treatment option of cardio-metabolic diseases, such as type-2 diabetes, non-alcoholic fatty liver disease, and obesity with marked effects on relevant clinical endpoints, providing new hopes for patients with unmet medical need. As their oral bioavailability is poor, these are typically injected subcutaneously, to lower administration burden and support adherence for patients in a chronic treatment home care situation.

The downside of this administration approach is its ecological burden as reflected in typically single-use devices combined with high injection frequency, e.g., weekly, over a long time period. Hence, these circumstances have triggered a tremendous focus on drug delivery device optimization for peptides as well as other modalities lately.

Initial approaches that aim to improve the ecologic footprint look at different, and often complementary angles, e.g., replacing plastics with bio-based variants[1] or using reusable devices[2]. However, achieving a significant step-change with these approaches is challenging as the backbone of these solutions remains unchanged.

Other emerging technologies may have a more profound effect such as drastically changing the amount of waste associated with injections but are facing other challenges. Examples include jet injectors[3], which do not require a needle and therefore no sharps disposal but have other issues which prevented a widespread use for drug delivery as for example usability. For oral delivery devices[4], the amount of waste in the patients' hands is comparable to a conventional oral formulation, but their clinical safety and efficacy profile as well as their reliability needs further investigation. Additionally, in case of non-biodegradable components, the waste management after excretion is not yet resolved.

Further complexity should be envisaged as next generation devices may combine several emerging technologies such as more innovative materials, a new device design, or are enabled by organizational measures like take-back schemes. We further envisage that any innovation that will lower the ecological footprint of drug delivery devices will require active feedback from patients and other stakeholders to increase acceptance, especially, should behaviorally changes in administration or handling be required.

Boehringer Ingelheim is dedicated to preserving the environment for future generations, with goals of achieving a CO_2 neutral balance and eliminating waste in landfills, among other endeavors. The company passionately seeks collaboration with visionary partners to develop groundbreaking ideas and concepts for the advancement of drug delivery devices.

As part of this opn2EXPERTS call, we invite you as an expert to propose concepts that clearly go beyond currently available as well as emerging solutions and envision a breakthrough in the challenging field of drug delivery.

Due to the complexity of the question, we think that the next generation innovation wave may come from scientists with very different backgrounds from either academia, start-up's, biotech's, or even the pharmaceutical industry. We are committed to come up with precisely tailored benefit packages that will help the winners of this call from various backgrounds to reach the next step towards clinical readiness with their proposed technological approach.

In summary, as part of this call we are looking for collaboration proposals that propose to overcome technological, conceptual, and economic hurdles associated with the development of sustainable next generation drug delivery devices.

What potential solutions could be in scope?

Prototypic, conceptual technology advances with convincing concepts, based on a clear rationale and hypothesis addressing one or several well-defined conceptual hurdles, but not necessarily having achieved a proof of concept. We prefer proposals focusing on reaching the next decision point or milestone towards clinical readiness.

- Technology concepts that provide a step change in sustainability of drug delivery devices beyond incremental improvements, even if safety and efficacy may not have been established so far.
- Novel combinations of emerging technologies or *de novo* solutions that have not yet been considered for sustainable drug delivery.
- Solutions that are either tailored solely for the delivery of peptides or enable to deliver both peptides and other modalities.
- Take-back schemes in combination with innovative technological approaches.
- In general, any technology solutions that are projected to reach proof-of-concept and clinical readiness within a timeframe of 5 to 10 years.

What potential solutions would be out of scope?

The following will be considered out of scope:

- Incremental improvements of current state of the art technology.
- Purely formulation-based approaches with the goal to lower injection frequency.
- Purely operational models to facilitate e.g., take-back schemes not involving any technological development.
- Solutions focusing solely on large volume modality device innovation.
- Apps and digital solutions intended to drive adherence (or more) which would improve ecological footprint mostly indirectly.
- Proposals from contract research organizations that are considered primarily fee for service.

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

This call represents a unique chance to make a significant impact in the field of drug delivery devices. By participating, you have the opportunity to collaborate directly with cross-functional experts lead by the Device Development team of Boehringer Ingelheim, a company deeply committed to innovation and sustainability.

We foresee that eligible solutions may come from scientists with very different backgrounds, ranging from academia, start-up's, biotech, or even larger enterprises such as device or pharmaceutical companies.

Successful proposals will not only contribute to a more sustainable future but will also be rewarded with tailored and scalable benefit packages along well-defined parameters.

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 in order to reach the next decision point or milestone towards clinical readiness.

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?

Our scientific review will address the following key success criteria for selecting winning proposals:

- The proposed solution must clearly go beyond currently ongoing approaches for sustainable drug delivery, should aim to reach market maturity with a timeframe of five to ten years, and address the in-scope and out-of-scope criteria of this call.
- 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.
- 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 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.
- An assessment about the expected net environmental impact is included.
- 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 non-confidential proposal (available for download on the following site).

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 **March 6, 2024, 11:59 pm PST** at the very latest
Phase 2	Our review of all proposals will be completed by end of April and submitting experts will be informed after that.
Phase 3	Potential collaboration starting date in Q3 or Q4/2024

Submitting a collaboration proposal

- Check the outline of the opn2EXPERTS "Progress sustainable drug delivery device technologies" 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 FAQ section on opnMe.com to learn more about our opn2EXPERTS program.

References

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3. Kelley E. L., Smith R.H., Gorcoran G., Nygren S., Jacoski M., Fernandes A. Advances in subcutaneous injections: PRECISE II: a study of safety and subject preference for an innovative needle-free injection system *Drug Deliv*. **2021**, 28(1):1915-1922. DOI: 10.1080/10717544.2021.1976309, PubMed.
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