

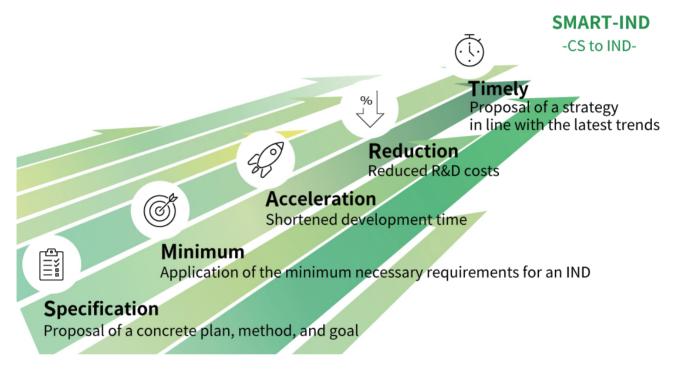
### IND-enabling package service

### **Smart-IND**

## ~Achieve the optimal IND using the fastest and most efficient way~

#### What is Smart-IND?

- •The optimal strategy based on your project goal and target product profile
- •Reduction in the time and cost by the efficient implementation of multiple studies at our one-stop shop
- A flexible plan for diverse modalities based on the accumulated experience of more than 100 INDs and 20 NDAs



## One team and one-stop shop

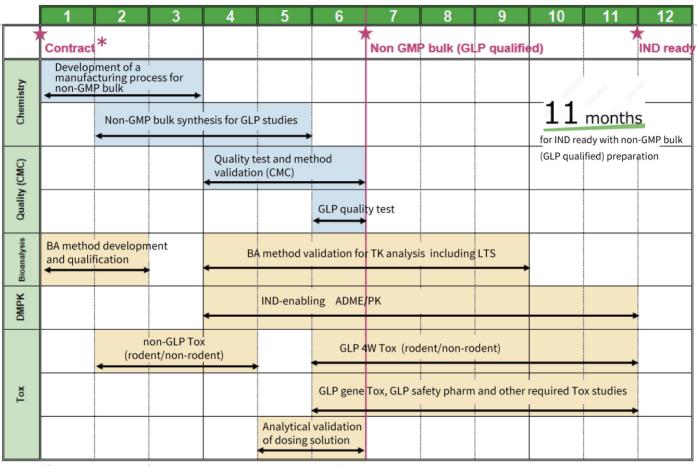
- A project manager and members who are well-experienced in pharmaceutical industries are assigned to each project in order to ensure smooth operation as one team together with the client.
- Various types of IND-enabling studies conducted in-house as well as at affiliated CROs are inclusively managed.





# Prepare IND data set in as little as 11 months

Before concluding a contract, Axcelead discusses the "target product profile," "strategic plan," "study design," and "synthetic route" with clients from the standpoint of the pharmaceutical industry.



\*: Sufficient amount of API with CoA is provided by a client.

Axcelead's chemistry team is ready to help establishing a practical synthetic route as well as prepare non-GMP bulk.

### Benefits of collaboration with Axcelead

Axcelead manages the entire preclinical study process and serves as a hub to significantly reduce the client's burden for IND.

- Achievement of an optimal IND based on the project goal and target product profile.
- •Implementation of the best package plan according to various modalities (e.g. Incorporating safety pharm and/or *in vivo* MNT to repeat tox studies, animal selection for repeat tox (KI/KO animals, appropriate single species, etc.), omitting *in vitro* studies, etc.)
- •One-stop access to the necessary functions/technologies of Axcelead and partner CROs and CMOs
- •Smooth transition to clinical development through further quantitative evaluation of projects by combining pharmacometrics, such as modeling and simulation, as well as PK/PD assays and analyses.