At PhinC Development, we help you identify, mitigate and overcome all the challenges you may face during your drug development process

PHINC DEVELOPMENT

Innovation . Agility . Expertise

PhinC Development

Your PK Modeling & Simulation Partner

OUR DNA

PhinC Development is today a key player in Europe when it comes to the use of modeling and simulation approaches during the drug development process. Thus, the uniqueness and strengths of PhinC strategy are based on the following 3 axes:

Deep Learning: It consists in developing the best models to exploit all the research data at every phase (in vitro, in vivo animal and human) and to carry out robust simulations and predictions that are acceptable for drug agencies (EMA, FDA, etc.).

Tailor-made support and advice: PhinC supports its partners from the first phases of development and brings its experience, informed recommendations and a Pharmacometric Modeling strategy adapted to each development program.

Agility and Biotech orientation: PhinC adapts its work organization and directs its collaborations to meet the needs and specificities of Biotechs (funding method, attrition rate, interaction with many other research providers, advice upstream on the development strategy, justification of the benefit of modeling, etc.).

INNOVATION

Faced with these major obstacles and challenges, PhinC brings its expertise in pharmacometry, pharmacokinetics, pharmacology and biostatistics to develop innovative predictive models. **Such models are now extremely powerful tools, able to give Biotechs a decisive advantage in the race to develop drug candidates.** Indeed, they make it possible to respond to a multitude of «challenges»:

1. **the increasing complexity of test protocols:** our models make it possible to evaluate several parameters simultaneously, to isolate particular effects, and to quantify their pharmacological effects alone or in interaction;

2. **the multiplication of data sources:** our models allow for the consideration of literature data, in vitro, in vivo on the species studied. In addition, these models will be fed and enriched progressively with the data that will be obtained during development;

3. **risk managment :** of cardiac, renal or hepatic toxicity, for example by modeling drug exposure versus toxicity biomarkers (troponin or QT wave for cardiotoxicity, for example), by helping to choose the first dose to be administered to humans thanks to inter-species predictive models;

4. **ethical requirements and cost reduction:** our predictive models make it possible to predict the systemic or target exposure levels of the candidate under study, with a sufficiently well-defined margin of error to reduce the scope of the different doses of the drug to be tested. This enables the optimization of the number of individuals (animal, human) or samples to be included in the experimental designs;

5. **the need for « derisking » :** our models make it possible to anticipate the therapeutic margin (between toxicity and the desired pharmacological activity) so as not to embark on a development with too narrow a therapeutic margin. Likewise with the risks of drug interaction (with statins for the elderly, for example), or modification with food intake, etc.

TAILOR-MADE SUPPORT

In 2019, France has 720 biotechnology companies, which ranks it 3rd in Europe after Germany and the United Kingdom. The sector is particularly dynamic since 60 new biotech companies are created each year. Indeed, the French ecosystem is favorable to the development of biotechnologies with, for example, the eligibility of R&D expenditure for the research tax credit.
To support these biotechs in their development programs, PhinC, as a specialist and pioneer in France in its field, puts all its expertise at their disposal.

In contrast to the large CROs known as «full services», PhinC has a collaboration model that is based on the long term and on the acute knowledge of the drug candidate and its context. As a PRO (Partner Research Organization) expert in modeling and pharmacokinetic simulation, PhinC has already accompanied numerous Biotechs from the selection of the candidate to the filing of the MA, thanks to a strategy that adjusts to the needs of each phase and to the regulatory demands.

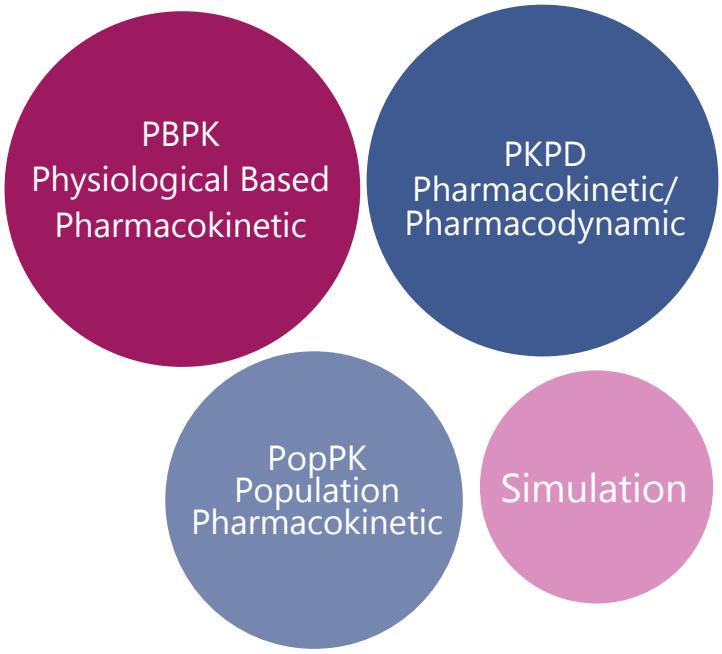
A commitment to Biotechs

Thanks to its ability to adapt, our model focuses on Biotechs, which constitute a strategic sector in the development of new treatments. More than 2 thirds of new drugs now come from it, especially the most innovative. Over the past 3 years, approximately 50% of Marketing Authorizations (MA) granted by health agencies have been for drugs directly or indirectly derived from biotechnology and the number of patients worldwide already benefiting from the advances made by biotechnology, both in terms of diagnosis and treatment is estimated at almost 500 million.

EXPERTISE

As early as the 2000s, the founders of PhinC Development had anticipated the growing importance that pharmacometrics would take on in the drug development process. Since 2008, we have gradually provided PhinC Development with all the expertise and capabilities that currently constitute the arsenal of Modeling and Simulation techniques recognized by the FDA and the EMA. This range of techniques and expertise allows us to develop predictive models for the most complex drug candidates.

These tools make it possible to develop a modeling strategy integrated into the development of the drug candidate. This strategy is also known as MIDD or MBDD (Model Informed/Based Drug Development).



The MIDD approach allows us to have a global vision of your development program to be able to provide biotechs with perfectly customized advice. At PhinC, we adapt to your way of working in order to be an integral part of your team and to be able to advise you rationally. We offer personalized support throughout the development process. So you will have all the keys to make a decision with peace of mind.

In a nutshell, the MIDD approach makes it possible to predict the results of the next stages of development with reasonable uncertainty and thus to optimize the animal and human experimental phases thanks to the application of the principle «learn, predict and confirm» in an iterative manner during the successive phases of development of the drug candidate.

Our MIDD model is perfectly suited to support biotechnology companies with proven experience with more than 180 of them.

Sources : Business France, French Biotech, FDA Reports

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