BIOTECH OUT-LICENSING OPTIMIZED COMPOUND VALUE

Product Oriented Licensing Strategy

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Optimized Compound Value Through Licensing Strategy

Executive Summary

intilaris LifeSciences is addressing key challenges of licensing clinical compounds developed by a biotech from a pharma company perspective.

Biotech companies benefit from intilaris Clinical Development expertise gained in leading pharmaceutical companies. intilaris guides Biotechs in the Exploratory Clinical Development strategy of Biotech compounds in essential Phase I Healthy Volunteer trials and Phase IIa PoC Patient trials.

Our Clinical Development strategy generates the essential Clinical Compound Knowledge which maximizes the Biotech out-licensing value and optimizes in-licensing into Confirmatory Clinical Development from the pharma perspective.

Applying our Gated Study Planning methodology for all essential Clinical Trials and using our Structured Study Definition model to capture key Clinical Protocol information, intilaris ensures and facilitates the transition of the Clinical Compound into the Pharma Clinical Development Program.

intilaris proven methodology and model is delivered through our Clinical Development Center of Excellence as a service to major Pharma companies conducting their Exploratory and Confirmatory Development Programs.

In this publication, we discuss several options to engage with your Biotech company and collaborate with you on the strategic planning of the value-optimized Clinical Development of your compound to ensure the successful medical product development – to your and your licensing partners advantage.

ASSUMPTIONS

To clarify the scope of our approach, we have made assumptions which we consider essential for the purpose of understanding our proposal:

- Biotech company identifies and patents compounds for innovative new drugs and/or treatments
- Biotech develops a compound with the out-licensing to Pharma in mind
- Out-licensing would aim to maximize the compound value (licensing fee)
- Co-development with your pharma licensing partner is a valid option
- Lifecycle management is another valid licensing option
- Biotech's clinical expertise is underrepresented
- Biotech would aim to develop a compound up to PoC (successful Phase IIa) or "as far" as it can, given its resources
- Biotech embraces the final medical product and aims for a successful product development collaboration
- Biotech collaborates with CRO's to conduct essential Clinical Studies

CHALLENGES FROM PHARMA VIEWPOINT

We consider challenges experienced by Pharma companies, while in-licensing a compound from an innovative Biotech, from at least three perspectives:
Clinical, Study and Integration perspectives.

Clinical Perspective

1. Limited internal infrastructure
2. Under-represented clinical knowledge with no specific or connected data across trials
3. Insufficient clinical safety and/or clinical efficacy data
4. Details on targeted unmet medical need

Trial Perspective

1. Lack of TPP claim details
2. TPP claims are not adequately supported by trial data and design
3. No or inappropriate CDP

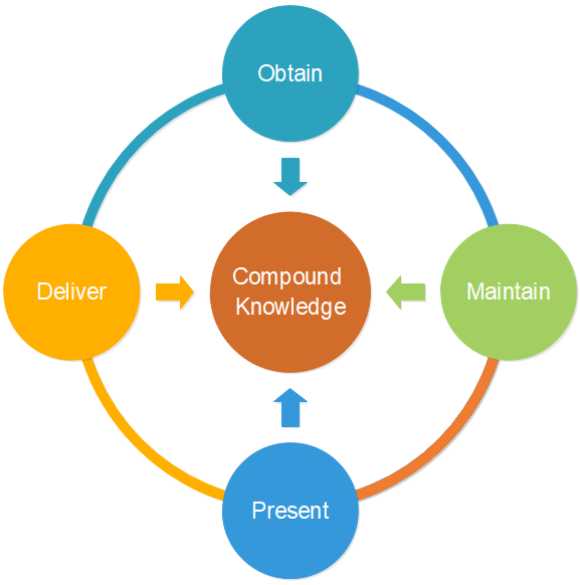
4. Reproduction of results hard to reproduce
5. Inadequate trial designs and protocols
6. Lack of continuity capability (to continue development in pharma)
7. Insufficient study population knowledge
8. Insufficient clinical knowledge of the compound

Integration Perspective

1. Different, inconsistent or no Medical Standards
2. Different, inconsistent or no Data Management Standards
3. Provided data cannot be integrated into pharma program
4. Lack of Clinical Project vision and strategy

METHODOLOGY

intilaris addresses the given challenges by utilizing our methodology proven in our Pharma services – Guided Study Planning (GSP), which qualifies the protocol information at Protocol Quality Gates and provides it at the earliest point in time. To capture that structured information, we use our Structured Study Definition (SSD) model.
Using such methodology and model, we apply standardization to the entire compound development program in biotech development phase, which in turn, enables smooth transition to pharma clinical program.
Derivation of regulated documentation such as Clinical Protocol is automated from the SSD model and can be delivered in any required template, including Transcelerate Clinical Protocol Template.
Our methodology ensures that all relevant Clinical Compound Knowledge is captured and managed outside of documents and is available for transition into pharma development.



1. **Obtain** - Through Biotech research - TPP and CDP
2. **Maintain** - Utilize intilaris framework - Gated Study Planning
3. **Present** - Structured Study Definitions
4. **Deliver** - Clinical Study Protocol, eCRF, CDISC Study Design, Drug Supply concept

PROPOSAL

Utilizing our expertise, know-how and methodology we provide:

- Seamless continuity of the biotech development into pharma
- Extension of Clinical Expertise into Clinical Development
- Phase I - Healthy Volunteer program approach
- Enable Biotech to benefit from existing knowledge and initiate the lifecycle management aiming to treat patients in further indications

Why work with intilaris LifeSciences?

intilaris supports the development of a working Clinical Development strategy.
In collaboration with your compound experts we design essential studies, create draft protocols and facilitate collaboration with CROs.
The final innovative medical product in mind, we work backwards and identify the essential trials. We help to design effective studies, create consistent protocols and maximize thereby the value of your compound.

Ready for pharma's Confirmatory Clinical Development – and your and your licensing partners success.

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