Collaborations avec l'industrie

l'exemple de Debiopharm International

Université de Genève

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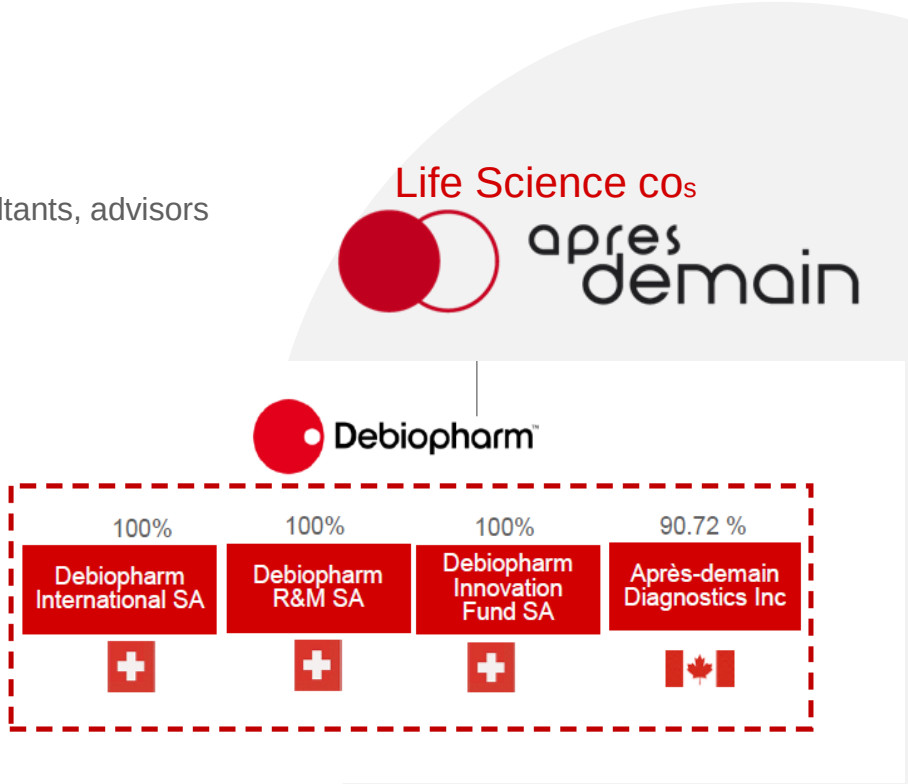
General Counsel

Senior Executive Director IP & Legal Affairs
& Pre-Commercial Alliances

Debiopharm : Key Features

- **Privately-owned:** financially independent
- **Headquarters:** Lausanne, Switzerland
- **Operational centres:** **Lausanne, Martigny**
- **Team** : staff around 400
- **International network:** over 400 experts, consultants, advisors
- **Key expertise :** drug development
- **Track record:** 5 products marketed



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What we do: Critical Achievements

44 years

of expertise in drug development since 1979

2022

1,400,000

Patients

Colorectal, prostate & pancreatic cancers

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Our Patient-centric Business Model

1 Drug Project

Licensor:

- Academia
- Biotech
- Start-up
- Pharma

Innovation

2 Creative Drug Development

Clinical Strategy
Market Access
Project & Lifecycle Management

3 Patients

Licensee:
Mid-size & Big Pharma

Commercialization

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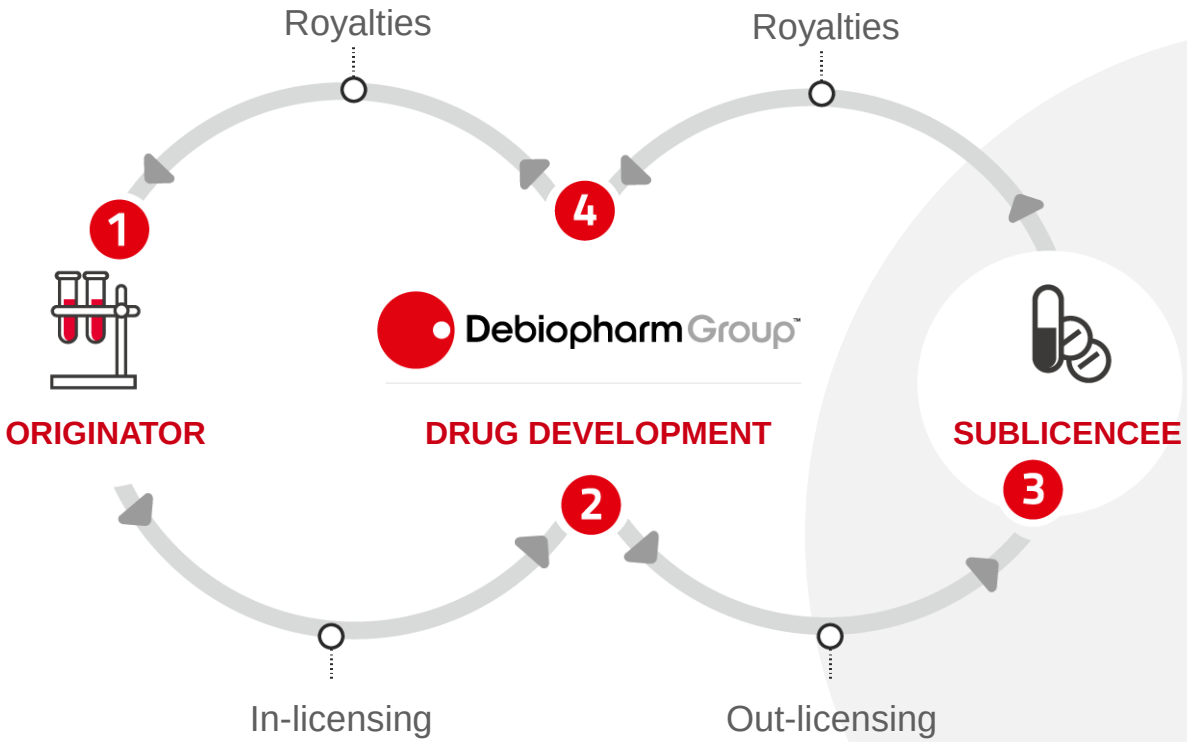
Relationships with our Partners



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Different types of collaborations with Universities

- **Confidentiality agreement** (CDA)
- **Consultancy agreement / speakers**
  (in a private capacity or on behalf of the University)

- **«Endowment» agreement**
- **Prize financing**
  (Japanese Cancer Association: JCA Mauvernay Award)
- **Partnerships including chair funding**
  (EPFL - IMD)
- **Sponsoring of events**

- **Material transfer agreement**
- **Service agreement**
- **Research & Development agreement**

- **Master Service agreement**
  (UNIGE, CHU de Québec (Laval), Uni de Milano, Univ. of Nottingham)
- **Master Research agreement**
  (HES-SO VALAIS, CHUV)

- Equity Investment in start-up (University spin-offs):
  (Diagnoplex, Spinomix)

IDEAL INNOVATION DEBIOPHARM ACADEMIA LEMAN

- early project funding, exclusivity, if interested, negotiation of a new contract

- Licensing IN : (University of Michigan, Paul Scherrer Institute (PSI))

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IP strategy framework & constraints

Specificity of Debiopharm business model

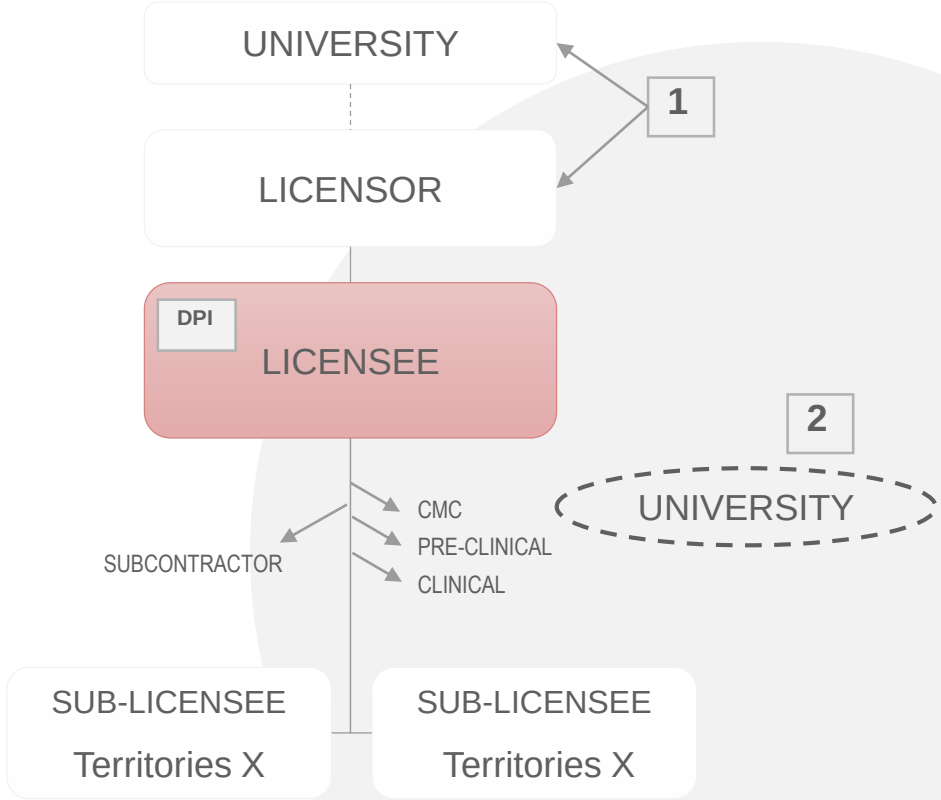
Assets or In-licensing for: Outlicensing

The In-licensing contract concluded for a molecule (for this and all other contracts related to this project)

- Confidentiality
- Publications
- IP Rights: ownership/exploitation
- Insurance
- Guaranties
- Termination

Perspective of out-licensing contract

- Secure the essential elements for marketing by our partners



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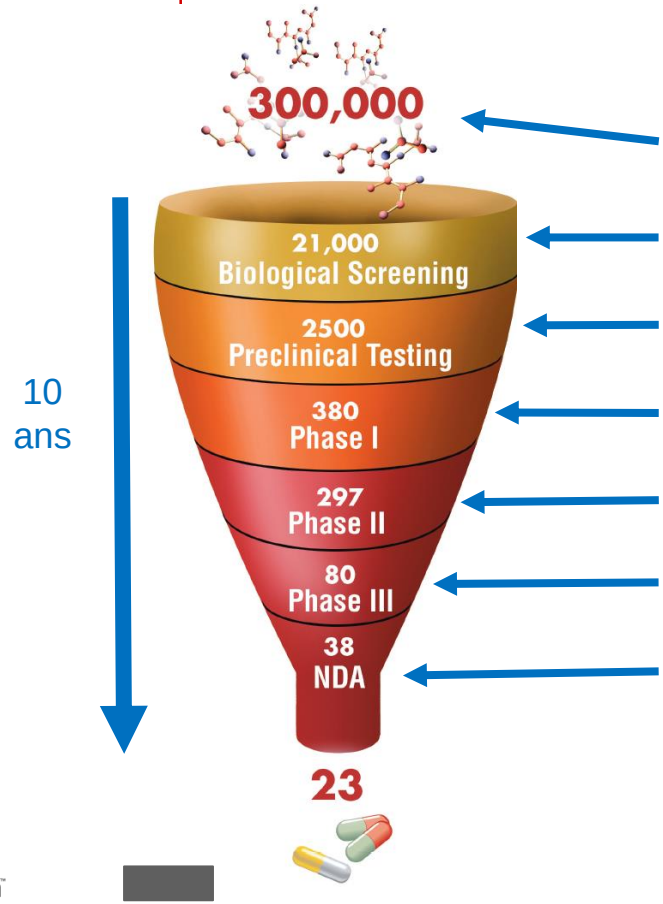
Development is very risky!



Taux de succès

0.008% des brevets

0.1% des screenings pré-cliniques

0.9% après évaluation pré-cliniques

6% des projets en phase I

8% des projets en phase II

29% des projets en phase III

61% des projets en demande d'AMM

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IP Goals, challenges, Strategy

Ensure the freedom of exploitation (FTO) of commercial drug candidate (DC)

- If you don't have FTO, licensing IP may be an option

Secure patent protection

Solid patent/enforceable
Encompass main competitors' product
Follow competitors and take measures

- **Don't** publish before you file!
- Go for broader claims, but specifically protect the DC (aim for strong DC protection)
- The more data the better
- Accelerate examination in key markets, a granted patent is more valuable than a pending one!

Preserve a longer exclusivity period (after data exclusivity)

- Strategize & plan the timing of patent filings & publications
  - Don't file too early, a later expiry is better
  - Don't file too late (think about competitor activity)

Balance Risk

- Manage the life-cycle:
  - try to obtain follow on patents around DC e.g. formulations, 2nd medical uses,
  - think of ways to block work arounds (be opportunistic but watch $$$)

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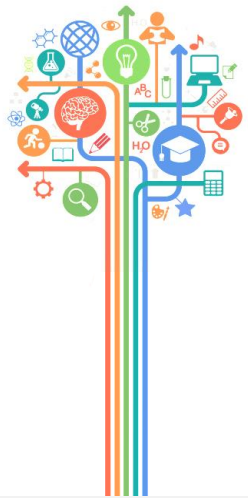
What we are looking for: In collaboration with academia

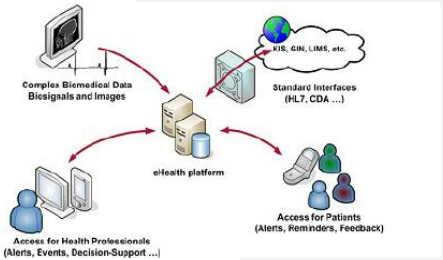
1. **Licensing IN Projects / Acquisition**:

- New Chemical Entity and New Biological Entity
- In oncology: all types, no vaccines, focus on targeted therapies
- In infectious diseases: antibiotics against multi drug resistant bacteria

2. **High level of expertise / competences to**:

- Develop cost effective drug / a diagnostic arm
- Redesign molecules
- Enhance patient access in emerging economies
- Explore new technologies, generate valuable knowledge
- Find solutions to solve a specific existing problem
    - E-health





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Collaborations with academia: our expectations

- **What do we look for when reaching out to a Professor for a collaboration?**
  - His expertise and valuable opinion in the field of interest
  - Well-known KOLs allow to improve the credibility of our project and to capitalize on their network
  - The presence in his lab of a specific technique, animal model, or access to relevant clinical samples

IDEAL INNOVATION DEBIOPHARM ACADEMIA LEMAN **concept** :

- Maturation of an early program of potential interest for a licensing

- **<u>Local contacts are privileged</u>** as communication is easier and frequent F2F are possible, however this is not an absolute requirement

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How to identify academics / How to proceed

How do we find who we could collaborate with ?

- Personal networks within our organization
- From the literature/conferences/university websites/consortiums
- Scouting team when looking for new opportunities
- Influencer Map: visual representation of the landscape of influencers of relevance to a project and how they are connected
- Digital scouting based on AI (identification of new opportunities from automated Pubmed search (developed in-house)

How to proceed, 2-step process:

- Non-confidential info to be exchanged (package for Licensing IN)
- Signature of a CDA (2 ways) to exchange confidential information

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What we expect to receive for In licensing project-1

Information Package (not a 1 page document)

- **Tell a story, talk about the future market,** don't talk about the history of the research
  - Short power point presentation with non-confidential data (a patent application is not enough)
  - Sell your product:
    - Indication, medical need
    - Type of molecule
    - Relevance of target, describe MOA
    - Stage of development:
      - *Efficacy data*
      - *Safety data*
  - Important to highlight therapeutic areas and development stage: (we want to see in vivo efficacy data)
  - Unique properties of your project: differentiation from existing technologies/products
  - **Disclose potential issues, we will find out eventually anyways**

Provide as much data as possible!

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Practical issues: when negotiating an agreement

1. **Preparation: who shall sign ?**
   - Under their name or the name of the University?
   - Who is authorized to sign
2. **Who shall Approve ?**
3. **Invoice / costs:**
   - Invoices to be sent regularly
   - Transparency regarding costs

«Entre le moment où nous avons envoyé le contrat signé et le moment où nous l'avons reçu il s'est passé 9 mois et l'Université a souhaité faire des amendements juste après, j'ai refusé»

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Practical issues : contracting party

- **Preparation: who are the contracting Parties to the Agreement?**
  - Is the agreement under the University or directly with the Doctor/expert/private person?
    - The contracting party receives the funds
    - Certain internal rules may apply to the employee of the University (eg regarding assignment of IP rights or utilization of University premisses/materials)

«Les universitaires ne vérifient pas auprès de leur service juridique ou direction pour savoir s'ils ont le droit :

- *d'accepter des **mandats de consultant indépendant : «** il est arrivé qu'on doive préparer un nouveau contrat au nom de l'employeur».*

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Practical issues: approval and signature

Who is authorized to sign?

- Not all employees of the University may sign for the University
- Sometimes the agreement might need to be validated by the legal department / tech transfer before it can be signed
- Double signature?

«Les universitaires ne vérifient pas auprès de leur service juridique ou direction pour savoir s'ils ont le droit :

- *de **signer pour le compte de leur employeur**. Il est arrivé que le consultant ait signé le contrat alors qu'il n'y était pas autorisé, du moins pas en signature individuelle.»*

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Practical issues: signature

- Not all Universities accept electronic signature (accepted by UNIGE)
- Email requesting signature might go into the Spams (→ delays)
- Depending on the electronic signature system used, it might be more or less complicated to sign
- Be careful to use the correct email address for electronic signature
- Original signature takes longer

Practical issues: Invoices

- **Invoices:**
  - should be sent regulary
  - should contain details to identify clearly the services/tasks
  - should make reference to the agreement
  - Should contain complete bank information

«Ils facturent tout en une fois à la place d'envoyer des factures régulières et/ou ne donnent pas suffisamment de détails»

"After termination of a project, done in collaboration with 2 professors in the same university, the University sent us a "final invoice" for the non-cancellable costs. 1½ years later, a second "final invoice" arrived from the University, mentioning these were the non-cancellable costs for the second professor"

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Practical issues: GOVERNANCE

- **Lack of communication and governance problems**

"Professor was managing the research in his lab as if he was the owner of the project. We were not empowered, and the decisions we made were not followed"

«une fois le contrat signé, les scientifiques se parlent et ne prennent plus en compte le contrat: ni l'objet du contrat, ni le temps consacré qui était prédéfini. Ce qui entraîne beaucoup de difficultés»

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Practical issues: DIFFICULTY TO COLLABORATE

- **Unwillingness to collaborate and share the knowledge**

"As a condition for a collaboration with his lab, a professor required a consultancy agreement. This agreement had to be done on his own terms: a monthly payment fee without notion of number of hours worked, and no requirement of written reports"

"The same professor, when solicited for consultancy, was systematically unwilling to commit and share his knowledge: we paid him for nearly 1½ years for almost nothing in exchange"

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Conclusion: Collaboration YES, IF ….

Implement collaborations where:

- Exclusivity on our Project : preserved/enhanced

Monitoring the risks:

- Free exchange of ideas/timely dissemination of results

Alignment on goals/needs: is key

- Need to clearly define goals and responsibilities

Agreements negotiated on a case by case basis

- But academics need to be prepared

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Time is of the essence!

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Thank you
for your attention

Do you have any questions?

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Contact information

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Title

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Debiopharm™
Headquarters

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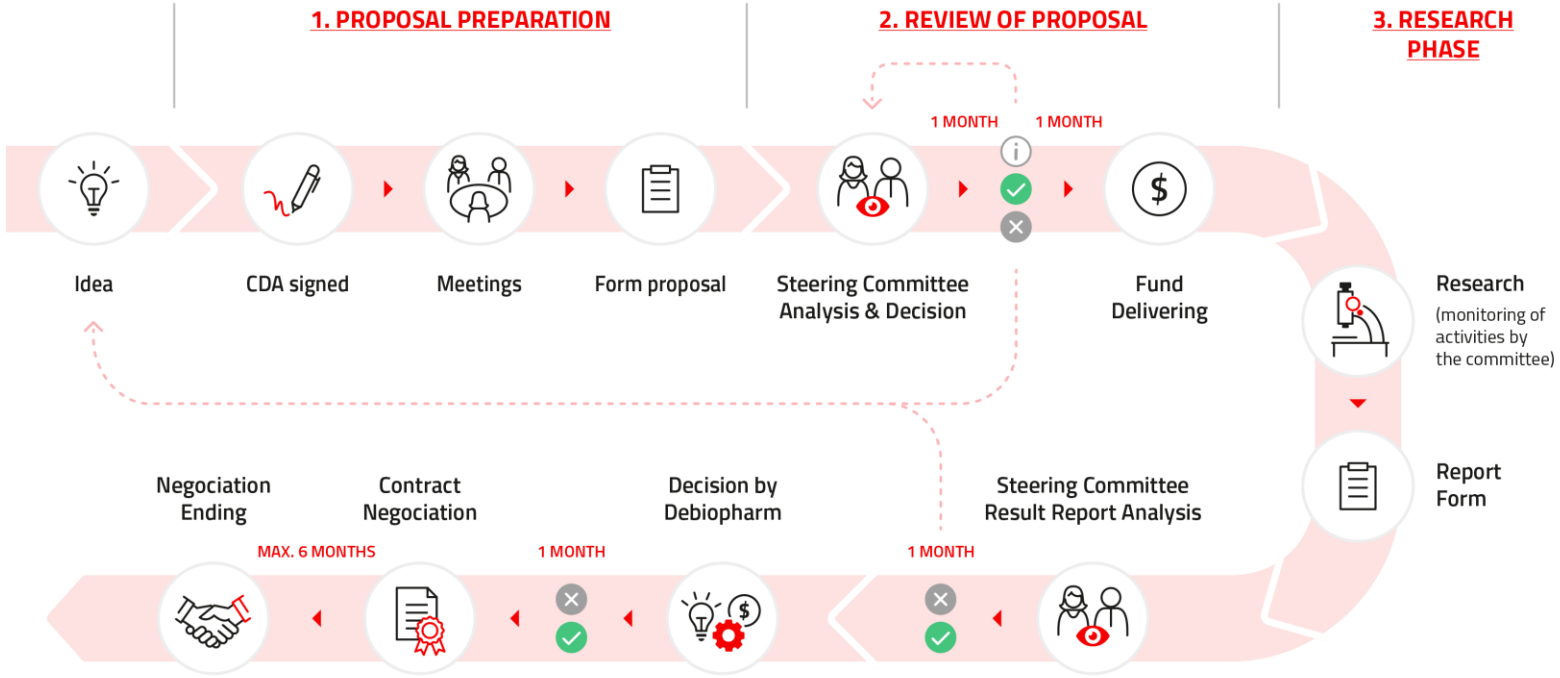
Fonds et durée initiale du Programme

- Max CHF 200’000 par année civile
- Environ CHF 5’000 à 50’000 par projet (max CHF 50’000); la somme comprend les overheads mais pas la TVA.
- Pilote sur deux années contractuelles. Sur la base du pilote, les parties discutent et DPI/DPRM réévaluent le montant pour les deux années suivantes
- Renouvellement automatique de deux ans en deux ans, sauf résiliation écrite avec trois mois de préavis
- Debiopharm peut à tout moment décider à sa discrétion d’augmenter le montant total par année contractuelle
- Reliquat éventuel d’une année contractuelle n’est pas rajouté aux CHF 200’000 de l’année suivante

The process


1. PROPOSAL PREPARATION
2. REVIEW OF PROPOSAL
3. RESEARCH PHASE
1 MONTH
1 MONTH
Idea
CDA signed
Meetings
Form proposal
Steering Committee Analysis & Decision
Fund Delivering
Research
(monitoring of activities by the committee)
Report Form
Steering Committee Result Report Analysis
Decision by Debiopharm
Contract Negociation
Negociation Ending
1 MONTH
MAX. 6 MONTHS
1 MONTH
5. PARTNERSHIP OPPORTUNITY
4. RESULT REVIEW

Exclusivité, confidentialité, propriété intellectuelle, publication

- **Exclusivité:** l'exclusivité s'applique au chercheur et à son équipe dans son laboratoire
- **Confidentialité:** Confidentialité des informations de chaque partie et des projets IDEAL (obligations de confidentialité standards + chaque partie a le droit de conserver les données pour des raisons d'archivage); durée de protection: 3 ans
- **Propriété intellectuelle:** tous les résultats générés pendant IDEAL appartiennent à l'institution qui a obtenu le financement; pendant la période du projet IDEAL, il n'y aura pas de dépôt de demande de brevet.
- **Publication:** droit de l'institution de publier les résultats, mais au plus tôt à la fin du projet IDEAL. Liberté totale de l'institution de publier dès que Debiopharm a décidé qu'il n'était pas intéressé. Si Debiopharm est intéressé, délai et conditions pour la publication négociés dans le nouveau contrat (droit de Debiopharm de revoir le projet de publication; délai pour déposer demande de brevet, etc…)
- **Communiqués de presse:** publication sur le programme IDEAL et sur l'existence d'un projet avec l'accord des parties concernées

Décisions de Debiopharm

délai de quatre semaines depuis le rapport final

OUI

Debiopharm est intéressé à ce que le développement continue:

- Négociation d'un nouveau contrat (achat, licence, collaboration, co-développement, etc…) qui tiendra compte du financement du projet initial par Debiopharm et de la prise de risque de chacune des parties (délai de six mois pour signer le contrat)
- Contrat entre Debiopharm et l'institut ayant bénéficié du financement IDEAL
- Exclusivité continue en faveur de DPI pendant la négociation du nouveau contrat et pendant le nouveau contrat
- Droit de publication: accord sur les délais et revue du projet par Debiopharm
- Conditions d'un éventuel dépôt d'une demande de brevet (décision par Debiopharm; demande déposée au nom de l'institution; frais à la charge de Debiopharm)

NON

Debiopharm n'est pas intéressé par les résultats:

- L'institut a toute liberté avec les résultats et le projet
- fin de l'exclusivité en faveur de Debiopharm
- Droit de publier les résultats de la recherche
- Droit de déposer une demande de brevet sur les résultats
- Encouragement à maintenir le contact et à représenter le projet si nouvelles données/brevet déposé

Peut-être…

- si intéressant, mais pas assez mûr: possibilité pour Debiopharm de pencher vers le oui et de faire une option
- si problème technique: possibilité de refaire si budget total reste inférieur à CHF 50'000 et uniquement une fois par année (ne doit pas devenir une habitude)

Si résultats non conclusifs:

- on bascule dans le **NON**