European Lead Factory

# Rights and obligations for Target Contributing Third Parties

| Rewards | Obligations |
|---|---|
| uHTS against unique Joint European Compound Library | Access rights and dissemination (IMI IP policy) |
| Full control of target programme progression | Compensation to EU Lead Factory in case of direct exploitation |
| Access rights and 3-year exclusivity to exploit screening results | First option right to EFPIA members to license target programme for direct exploitation (to be accepted at your discretion) |

## LEGAL PROCESS

When your Target Programme Proposal has been accepted and you have signed the Form of Accession, you are a 'Target Contributing Third Party' to the Project Agreement. This agreement regulates all activities that follow and the document is available for review in the online submission tool. The EU Lead Factory also operates within the framework of IMI's Intellectual Property Policy, which provides an overarching set of rules relevant to all participants.

## YOUR RIGHTS

**1. Screening**

Based on an upfront agreed programme plan, your selected Target Programme is screened against those compounds that are available within the Joint European Compound Library (JECL). Any 'threshold active' hits are then identified for further characterization and hit qualification.

All experimental work is performed by consortium partners in the European Screening Centre (ESC), supported by IMI funding. Your input may include assay materials (DNA plasmids, proteins etc) and hands-on experience with the assay for trouble-shooting.

European Screening Centre scientists will give you a 'Qualified Hit List' (QHL) of up to 50 compounds. Where meaningful, the QHL might also contain inactive structural analogues of threshold active hits, to provide a potential structure-activity relationship. In agreement with you as the programme owner and at discretion of the European Screening Centre, the ESC may also undertake additional activities (like resynthesis, DMPK, crystallography) that lead to an 'Improved Hit List' (IHL).

**2. Access Rights**

You will receive the access rights (or in case of IHL compounds even ownership) and 3-year exclusivity to progress QHL/IHL results. In order to give you enough time to progress to a potentially patentable set of data, all threshold active compounds disclosed in your QHL are made unavailable to other target programmes within the EU Lead Factory. During the 'exclusivity period' you are under no obligation to disseminate/publish screening results.

**3. Exploitation**
You are free to decide for your own Target Programme how results (in part or whole) will be advanced, for example by direct exploitation and/or research use. Please note that publication of results is subject to an option right for licensing granted to EFPIA Participants and the publication policy of the European Lead Factory as detailed below.

## YOUR OBLIGATIONS

**1. Access and publication**
The Consortium Agreement and IMI Intellectual Property Policy regulate access rights for all consortium partners and Target Contributing Third Parties during completion of the project and subsequent research use and/or direct exploitation.

As a Target Contributing Third Party, you grant non-exclusive royalty-free access rights to the Background you have on the Target Programme to the partners within the European Screening Centre necessary for them to perform the work on your Target Programme.

After expiration of the three-year exclusivity period, the following information of your QHL/IHL will be made available within the consortium via the Programme Office (Lygature): Programme Name, target, gene ID and mechanism of action. This information will be shared with the other consortium partners, however, your party name will not be disclosed. If another Partner is interested in obtaining research use rights for your Target Programme, such rights should be negotiated on Fair and Reasonable conditions in accordance with the Consortium agreement.
The results of the Target Programme have to be disseminated to the public in accordance with the timelines in the Consortium agreement (in general 1 year after the end of the project). However, this does not oblige you to publish each and every data point of the work that has been done.

Publication of scientific results is subject to a defined Publication Policy and related approval process, designed to protect confidential information and limit potential conflicts with consortium partners. Review and possible IP protection measures may delay submission for publication by a maximum of 45 plus 90 days, respectively. In addition, if there is an interest by an EFPIA Participant to negotiate for a license of the results for direct exploitation, there could be an additional 180 day delay.

**2. Payments**
Hit discovery and characterization are based on collaboration between you and the EU Lead Factory. On disclosure of the QHL/IHL to you, ownership of the results is transferred to you.

In the case of direct exploitation of your Programme, you agree to compensate the Party that has provided the relevant compound on your QHL via a scheme of milestone payments. These are triggered by defined events along the value chain, starting with patent filing (more specifically the PCT application), and require patent claims to include either a QHL/IHL compound or derivative.

A flexible payment schedule is provided, but the option for payment of the Patent milestone must be selected at the time the Target Programme is accepted. The list of milestone payments is the following for a pharmaceutical product:

- one of 3 patent milestone options: €50.000 with PCT filing, €75.000 within 2 years from filing, or 10% of the compensation your receive based on the Target Programme.
- additional (clinical) milestones including
    - IND filing: € 250.000
    - start phase II: € 750.000
    - start phase III: € 2.500.000

For a diagnostic product containing a QHL/IHL compound or a derivative, a single clinical milestone of €250.000 is due with market launch in the European Union, the United States of America, China, Brazil, India or Japan.

Licensing or transferring your Target Programme to a third party other than an EFPIA Participant of the European Lead Factory will trigger a one-time payment (€250.000 prior to IND filing and €1.000.000 after IND filing).

Target Programmes that relate to neglected tropical diseases as defined by the World Health Organization, may be granted the status of a Neglected Disease Target Programme upon selection. The consortium has decided to waive the clinical, diagnostic and ownership milestone payments for these programmes as long as the results will not be commercialized outside the Least Developed Countries. The patent milestone payment regimen remains for these programmes.

**3. Option to License**

By signing the Form of Accession, you will give EFPIA participants the right to submit a first offer on licensing your Target Programme. This is before publication or licensing to a third party, and at the latest upon expiration of the three-year exclusivity period. The option must include at least a non-exclusive license on the target of your target programme and all relevant background information, and an exclusive license on its associated QHL/IHL. If you cannot reach an agreement with any EFPIA Participant, you can then offer your programme to any third party, or you can continue development.

## MORE INFORMATION

More information is available after registration in the online target submission tool. If you have any questions, please use the online contact form and we will be in touch.

## DISCLAIMER

*Only the official and formally signed contractual documents in relation to the IMI-EUC2LID Project (the Project Agreement, Grant Agreement, the Description of Work, the Access Agreement for your Compound Design Proposal and Target Programme Proposal and the Form of Accession for Chemistry Contributing Third Party OR the Form of Accession for Target Contributing Third Party) have a binding value in relation to the subject matter covered in the pages of this document. Any information contained in the pages of this document is not binding upon the parties and can in no event be used to interpret or complement the formally signed contractual documents referred to above.*