Rights and obligations for Contributing Third Parties

Rewards	Obligations
uHTS or Phenotypic Screening against unique ESCulab Compound Collection (ECC)	Access rights and dissemination (IMI2 IP Framework)
Full control of target programme progression	Compensation to consortium members within ESCulab in case of direct exploitation
Access rights and 3-year exclusivity to exploit QHL results	First option right to EFPIA consortium members to license your Programme for direct exploitation (to be negotiated at your discretion)

LEGAL PROCESS

When your Programme Proposal has been accepted and you have signed the Contributing Third Party Agreement, you are a 'Contributing Third Party'. This agreement regulates all activities that follow, and the document is available for review in the online submission tool.

YOUR RIGHTS

1. Screening
Based on an upfront agreed programme plan, your selected Programme is screened against those compounds that are available within the ESCulab Compound Collection. Any 'threshold active' hits are then identified for further characterization and hit qualification.

All experimental work is performed by the public consortium partners of the ESCulab consortium, supported by IMI funding. Your input may include assay materials (DNA plasmids, proteins etc) and hands-on experience with the assay(s) for trouble-shooting.

The outcome of the Programme will be a 'Qualified Hit List' (QHL) of up to 50 compounds with associated biological data. Where meaningful, the QHL might also contain inactive structural analogues of threshold active hits, to provide a potential structure-activity relationship.

2. Access Rights
You will receive the access rights and 3-year exclusivity to progress the QHL results (subject to exceptions, e.g. in case of patenting and the EFPIA option process, see below). 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 screening 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 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 Contributing Third Party Agreement regulates access rights for Contributing Third Parties during completion of the project and subsequent research use and/or direct exploitation.

As a Contributing Third Party, you grant royalty-free access rights to the background ("Programme IP") you have on the Programme to the public consortium partners within ESCulab necessary for them to perform the work on your screening Programme.

Certain Research Use Access Rights on QHL results and background ("Programme IP") need to be provided to the consortium members. After expiration of the three-year exclusivity period (subject to the EFPIA option – see below), the following information of your QHL will be made available within the consortium via Lygature. For target focused programmes: Programme Name, target, gene ID and mechanism of action; for target agnostic programmes: Programme Name, biological specimen, trigger, response of interest, and time and mode of its quantification. This information will be shared with the other consortium partners, however, your name and organisation will not be disclosed. If a consortium partner is interested in obtaining research use rights for your Programme, such rights should be negotiated on Fair and Reasonable conditions in accordance with the Contributing Third Party Agreement. Such conditions may also include time delays for granting Research Use Access Rights, which may add up to six (6) years from disclosure of the QHL results in total.

The results of the Programme have to be disseminated to the public in accordance with the timelines in the Contributing Third Party Agreement. However, this does not oblige you to publish each and every data point of the work that has been done. Please note that publication of results is subject to an option right for licensing granted to EFPIA Participants, see section 3 below on the EFPIA option.

Publication of scientific results is subject to a defined Publication Policy and related approval process, designed to protect confidential information of and limit potential conflicts with consortium partners. Review and possible IP protection measures may delay submission for publication by a maximum of 50 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 9 months delay.

2. Payments

Hit discovery and characterization are based on collaboration between you and the European Lead Factory. On disclosure of the QHL to you, ownership of the QHL results is transferred to you.

In view of this transfer and the previously mentioned access rights, in the case of direct exploitation of your Programme, you agree to compensate consortium members for their contribution to your QHL via a scheme of milestone payments. These are triggered by defined events along the value chain, starting with publication of a first patent filing, and require patent claims to include either a QHL compound or derivative.

A flexible payment schedule is provided. The list of milestone payments is the following for a pharmaceutical product:

- one of 2 patent milestone options: (I) €55.000 with publication of every first filing of a QHL Patent Application, or (II) 10% of the compensation you receive in case of sale or out licensing a QHL compound, a Derivative, or products or diagnostics containing the same, or in case you commercialize a product or diagnostic comprising a QHL compound or Derivative yourself or through your affiliates, a royalty of 1% of Net Sales of such a product or diagnostic.
- 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 compound or derivative, a single clinical milestone of €250.000 is due with market launch in the European Union, the United Kingdom, the United States of America, China, Brazil, India or Japan.

Licensing or transferring your 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).

In case a Programme is defined as a screening programme that relates to a biological target specific to a causative pathogen as provided on the neglected tropical diseases list from the World Health Organization (check the current list at http://www.who.int/neglected_diseases/diseases/en/) or Malaria disease, and that is granted the status 'Neglected Disease Programme' upon selection, all the consortium partners have agreed to irrevocably waive their rights to milestone payments.

3. EFPIA Option to License

By signing the Contributing Third Party Agreement you will give EFPIA consortium partners the option right to submit a first offer on licensing your Programme. This is before publication or licensing to a third party, and at the latest upon expiration of the three-year exclusivity period. Shorter timelines apply in case of patenting. The option must include at least your rights to the programme, its associated QHL, and all relevant background information. If you cannot reach agreement with an EFPIA Participant that triggered the option, you can then offer your programme to any third party, or you can (dis)continue development.

MORE INFORMATION

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 IMI2-ESCulab Project, operating under the name of the "European Lead Factory", (the Consortium Agreement, Grant Agreement, the Description of Action, the Statement of Interest and the Contributing Third Party Agreement) 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.