Rights and Obligations for CTP screening Programmes

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 806948: *'ESCulab: European Screening Centre; Unique Library for Attractive Biology'*. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and Medicines for Malaria Venture.

Dear Reader,

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 these slides. Any information contained in these slides 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.

The European Lead Factory Team

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Contributing Third Parties (CTPs)…

Rights

Screening of a unique **Compound Library** at **Screening Facility**

Access Rights and 3 Year **Exclusivity** to Exploit Qualified Hit List Results

Full Control of Programme Progression

Obligations

Access Rights and **Dissemination** (IMI2 IP framework)

Compensation to consortium partners *- for Direct Exploitation only -*

Option for EFPIA consortium partners to license your Programme for Direct Exploitation

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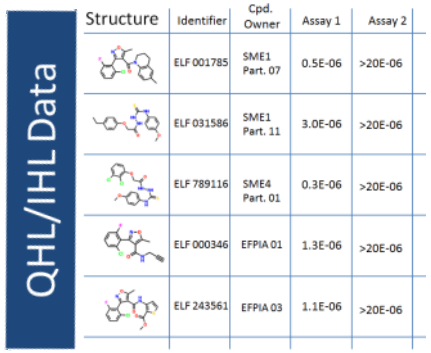
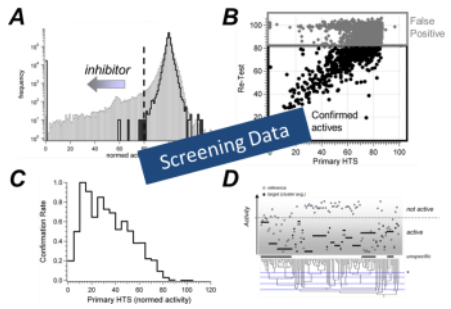
Contributing Third Parties Rights





Is the **sole party permitted** to exclusively perform any Direct Exploitation of QHL Results

Sole discretion **to decide** future exploitation of the QHL (research, development or commercialization)

Is provided a **3-year exclusivity period** to exploit QHL data i.e. no other Beneficiary can access such data during that period (subject to exceptions, e.g. in case of patenting and the EFPIA option process)

Is **granted Access Rights**, subject to certain specific terms, on the Results of other consortium partners (and Background considered necessary for the use of such Results) for **the purpose of Research Use** of its own Results.

Is **granted Access Rights (or a non-assert) by the Compound Owners** to certain of their Results and Background necessary for **Direct Exploitation of the QHL Results** subject to a compensation scheme (see Contributing Third Parties Obligations).

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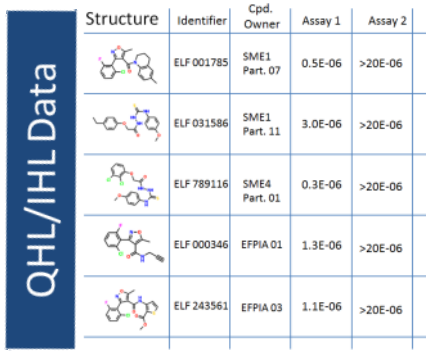
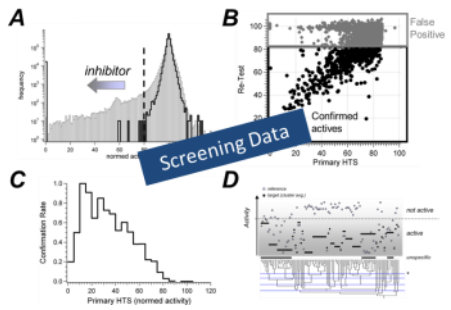
Contributing Third Parties Obligations





To **compensate consortium partners** for ownership transfer of QHL Results and Access Rights received from the Compound Owner for Direct Exploitation of the QHL by the payment of Milestones triggered by defined events

To grant to EFPIA Beneficiaries **the Option for Direct Exploitation** of a screening Programme and related QHL Results (EFPIA Option: 'first bid' for licensing)

To adhere to the **Dissemination Policy** (incl. approval process)

To **grant Access Rights on its QHL Results** (and background ("Programme IP") considered necessary for the use of such Results), subject to certain specific terms, to the other Beneficiaries for the purpose of Research Use; these Access Rights are subject to specific terms.

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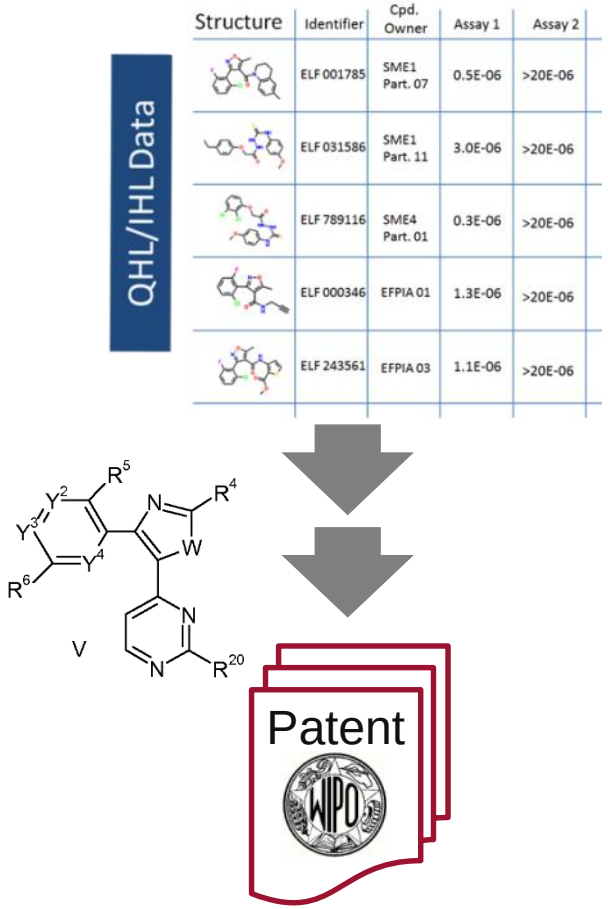
Milestone Payments Patent Milestone



Patent Milestone Event

- Triggered **by publication of every first filing of a QHL Patent Application** including QHL Compound(s) or Derivative(s) or a combination of these.
- Maximum of six Milestone Payments in total per Programme.

Milestone Payment

The Programme Owner has the following two options (except in case the Programme was successfully licensed, transferred, or otherwise assigned to an EFPIA Beneficiary, in which cases always option (i) applies):

Two Options (to be selected 17-18 months after patent filing)

(i) make a single, one-time payment of **€ 55,000** upon patent publication

(ii) a payment of **10% of the compensation** that such Programme Owner receives in case of sale or outlicensing a QHL compound, a Derivative, or products or diagnostics containing the same **or**, in case the Programme Owner commercializes a product or diagnostic comprising a QHL compound or Derivative itself or through its affiliates, **a royalty of 1% of Net Sales** of such a product or diagnostic.

→ if the Programme Owner intends to abandon the QHL Patent Application, or 5 years after the filing of the QHL Patent Application has not sold or outlicensed a QHL compound, a Derivative, or products or diagnostics containing the same: Single payment of **€ 75,000** or offer for assignment of QHL Patent Application to respective Compound Owner.

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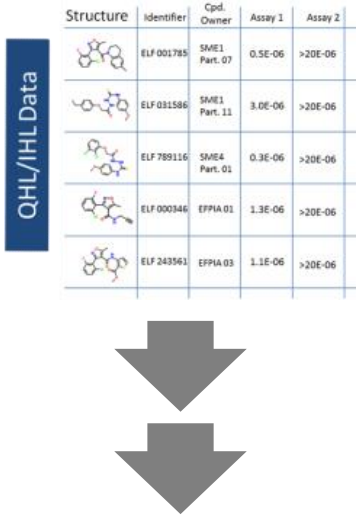
Milestone Payments Other Milestones



Clinical Milestones

for any therapeutic product containing a QHL Compound or Derivative

- First IND Approval € 250,000
- Start* Phase II, 1st indication € 750,000
- Start* Phase III, 1st indication € 2,500,000
- Further Clinical Milestones in limited cases
  (*dosing of 5th patient)

Diagnostic Milestones

for a diagnostic product containing a QHL Compound or Derivative

- First market launch in the US, UK,
  EU, China, Brazil, India or Japan € 250,000

Change of Control

upon licensing or transfer of a Programme to a Third Party

(a) before IND approval € 250,000

(b) after IND approval € 1,000,000

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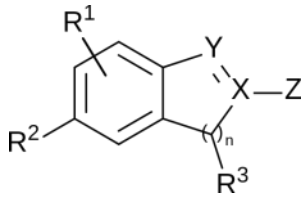
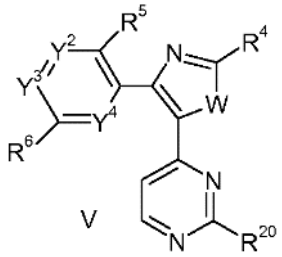
Derivative definition





Derivative(s)" means any compound which is not a QHL Compound and

(1) such compound:

(a) demonstrates Threshold Activity on the Programme; and,

(b) is within a Scaffold belonging to any QHL Compound of the QHL of the Programme; and,

(c) was first synthesized by or on behalf of the Programme Owner within three (3) years after disclosure of the Qualified Hit List to the Programme Owner; or,

(2) any base form, metabolite, prodrug, ester, radio-labelled or salt form, racemate, stereoisomer, crystalline polymorph, hydrate or solvate of any of the QHL Compounds or a compound defined in (1) above

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No milestones for Neglected Disease Programmes

Definition Neglected Disease Programme

Screening Programme that relates to a biological target specific to

(i) 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

(ii) Malaria disease

And that is granted the status 'Neglected Disease Programme' upon selection.

A transfer or sale of the Neglected Disease Programme or Product resulting from its associated QHL from the owning Beneficiary to one of its Affiliated Entities or a Third Party shall not cause such Programme to lose its Neglected Disease Programme status and shall not trigger the Change of Control Milestone.

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EFPIA Option: Access Rights for Direct Exploitation

Why?

- Provides Programme Owners with access to potential partners for Direct Exploitation
- Ensures value generation from European Lead Factory results
- Balances EFPIA's investments and interests by granting to EFPIA Beneficiaries option for first bid on innovative screening Programmes

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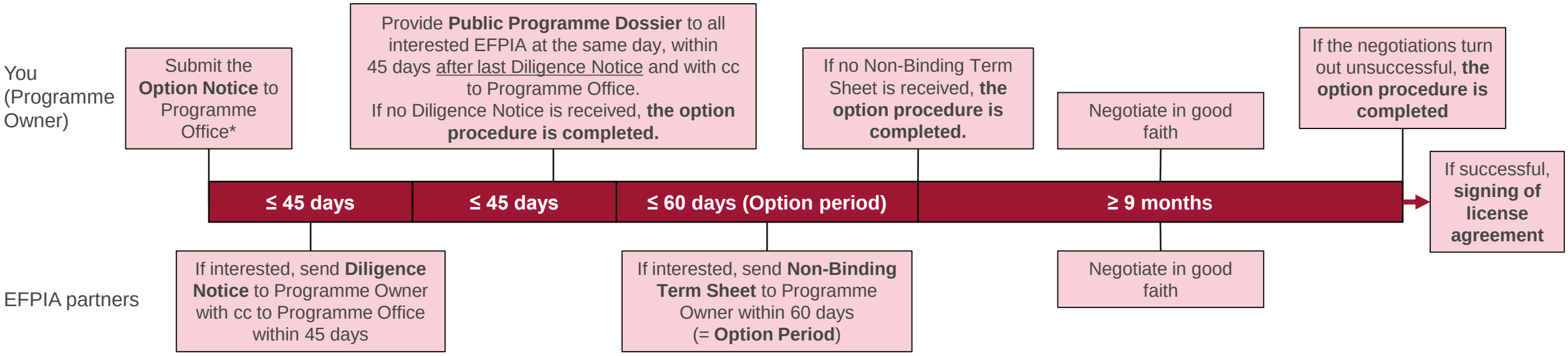
EFPIA Option process



*initiate option process 3 months after filing of first patent application on QHL Results (= priority patent application) or at the latest 3 years after receiving the QHL report.

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EFPIA Option: the rights to be offered

The rights to be offered under the Option Notice by the Public Programme Owner shall minimally include the following:

(i) a non-exclusive, worldwide license on the Public Programme for use for any purpose; and

(ii) an exclusive, worldwide license on all the rights it has on the associated QHL (including the right to prepare further Derivatives and to screen and evaluate other compounds on the Programme) for use for any purpose and the passing on of the right of non-assert under Clause 7.9 it enjoys from the respective Compound owners of the Compounds into the QHL; and

(iii) an exclusive, worldwide license on the associated Results to such Public Programme for use for any purpose; and

(iv) a non-exclusive worldwide license on any other Background (owned or controlled by the Public Programme Owner or its Affiliated Entities) Necessary to perform Direct Exploitation of (i), (ii) and (iii); and

In addition, to the extent not limited by contractual obligations towards Third Parties, it shall include the right to use and receive samples of all required biological and chemical materials (such as assay and target materials, proteins, compound samples, as appropriate), to allow the licensee to carry out further research, development and commercialisation of Products or Diagnostics in relation to the Programme.

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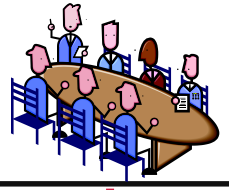
Dissemination: Publication Approval

submit **50 days** before planned dissemination

5 days for processing



Publication Approval Committee

15 day review period
(to ensure not harming value generation consortium)

NO! (unanimous objection)

rewrite & resubmit *or* delay

YES! (No unanimous objection)

Reasons for rejection (and duration)

1. Protection of consortium partner's Results (90 days)
2. Removal of confidential information (ASAP)
3. Potential harm to consortium partner's legitimate interests (should be resolved ASAP)
4. Partnering proposal (within 9 months)

Circulation to all partners

30 day review period

NO!

YES!

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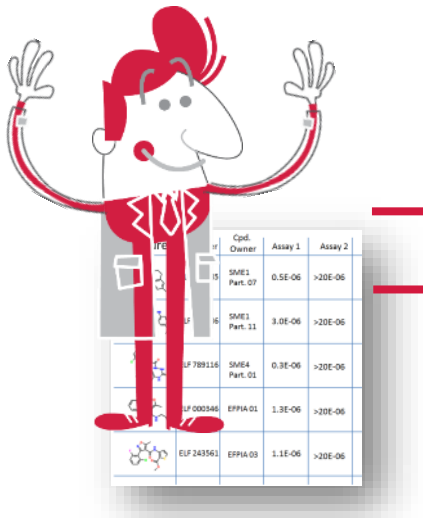
Summary



Qualified Hit List

3-year exclusivity period on use of QHL Results
Research or Direct Exploitation, exceptions apply

First option to EFPIA partners

EFPIA

Publication Approval

Patent

Milestone Payments

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Questions?

Please contact the Programme Office at

Programme@EuropeanLeadFactory.eu

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