# IMI2 Intellectual Property rules in light of Call 10 topics

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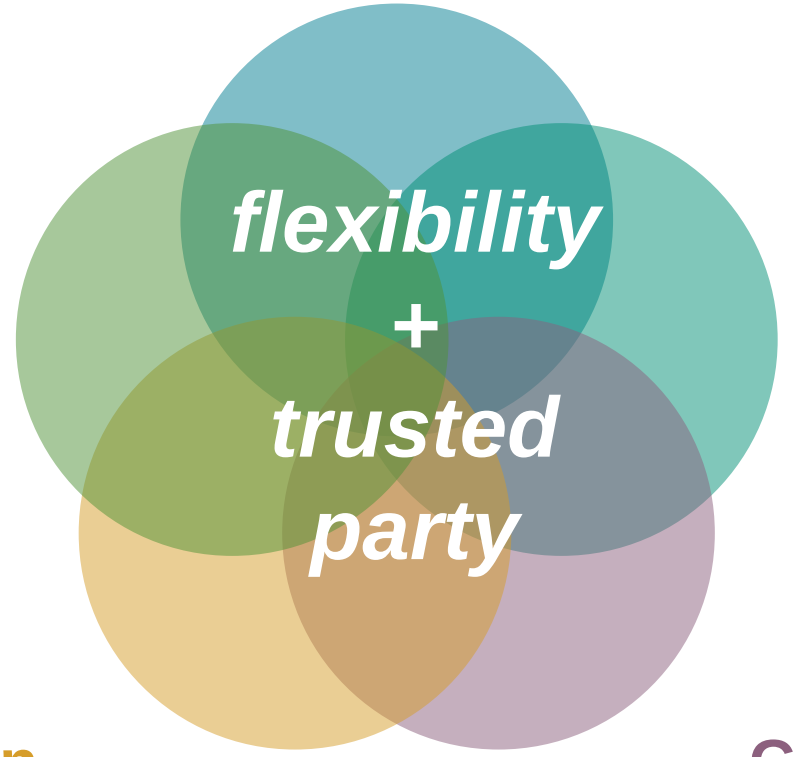
# One policy for multiple interests

Support to industry

Incentive to participate




Freedom of access

Dissemination of information

Compensation for IP

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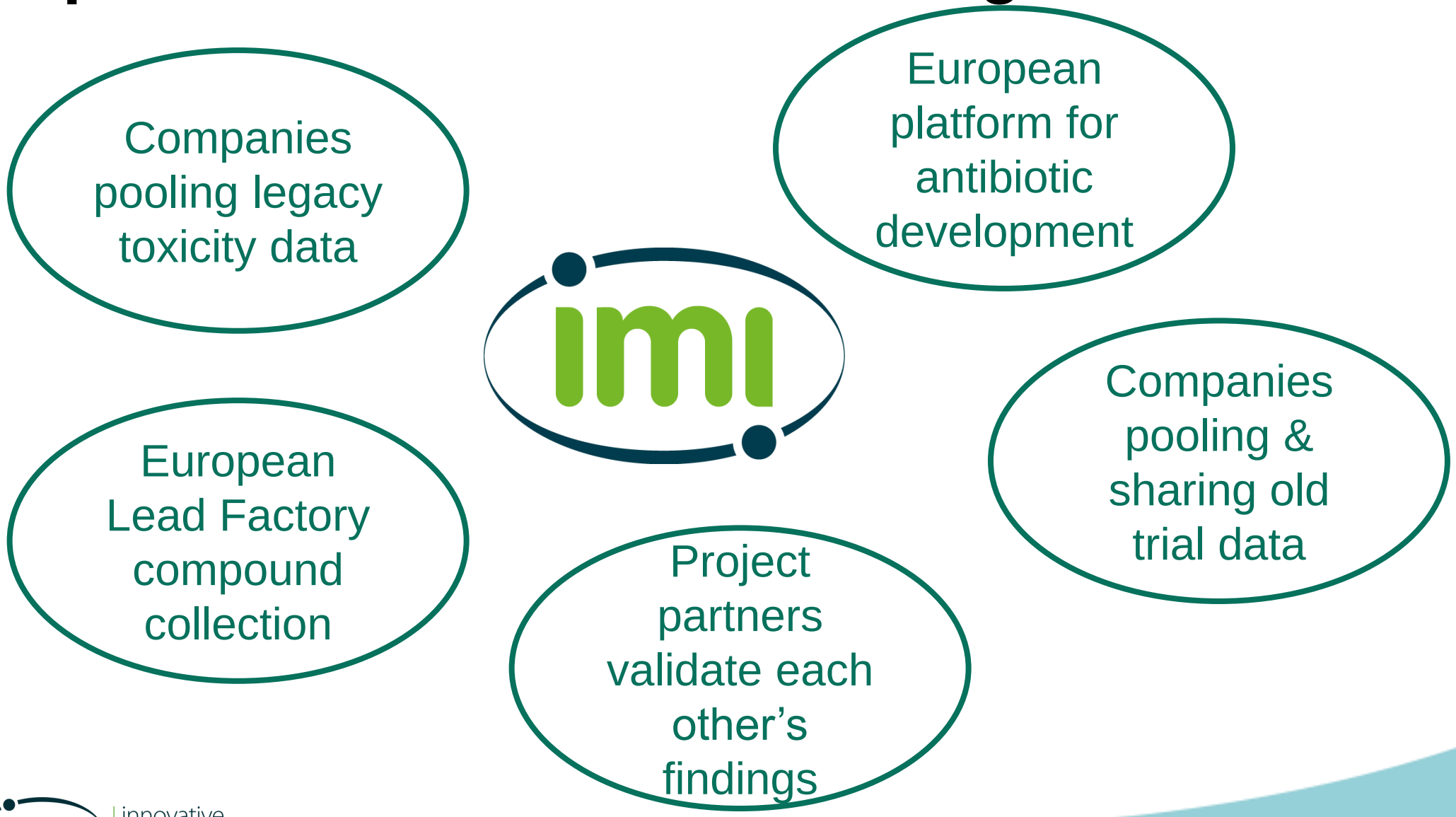
# IMI IP policy has already allowed unprecedented levels of sharing

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# Background, results, sideground

# Definition of background

***Article 24.1 IMI2 MGA***

- Different from IMI1

  Scope extended: Background includes materials

- Any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:
  - is held by the beneficiaries **before** they acceded to the Agreement,
  - is **needed** to implement the action or exploit the results, and
  - *which is **identified and agreed** by the Beneficiaries.*

- **All** conditions have to be met to be considered background and be subject to specific rights & obligations

# Some background from Call 10 topics

- **Understanding Hypoglycemia**: anonymized clinical trial databases of individuals, etc.
- **BD4BO research**: Genomic/clinical data, Statistical programs, databases, etc.
- **Chronic Pain**: Data stored in health registries, etc.
- **Paediatric CTN**: Patients data, Data science/statistics, know-how in concluding paediatric clinical trials, etc.
- **Biomanufacturing 2020**: Biopharmaceuticals, data handling tools, etc.
- **Unlock SLCs**: Vitro biology resources and reagents, Studies data, Assays, etc.
- **Enhanced patient voice**: Know-how in clinical development, business operations, DKM, regulatory, etc.
- **Autism**: Biomarkers, Clinical networks, etc.

# Ownership of background

- Each beneficiary remains the exclusive owner of its background

- Possibility to transfer ownership
  - within the consortium to affiliates and purchasers without prior notification
  - on case-by-case basis

# Background and access rights

- Grant of access rights to beneficiaries :
  - for action implementation (including to affiliated entities)
  - for research use of results
- Grant of access rights to third parties :
  - after completion of the action
  - for research use of results
  - possibility to exclude certain elements

**=> Importance of identifying Background**

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# Definition of results

## *Article 26 of IMI2 MGA*

- Same as IMI1

- Any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not
  - that is generated **in the action**, as well as any rights attached to it, including intellectual property rights
  - **excluded Sideground** - output generated by a beneficiary under the action but **outside of the action objectives** as defined in the Grant Agreement

**=> Importance of Action objectives**

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# Expected results from Call 10 topics

- **Understanding Hypoglycemia**: Standard guidelines, Information about new relationships between baseline characteristics and interventions, standardized collection of clinical and laboratory data, etc.
- **BD4BO coordination**: Central repository of knowlegde and information, Common standatrds for the collection, analysis and management of personal data, etc.
- **BD4BO research**: Protocols, processes and tools to access high quality data, Methodologies and analytics, Data sharing platform, Recommendations, etc.
- **Chronic pain**: Patient report outcomes measures, Clinical pharmacodynamic biomarkers, etc.
- **Paediatric CTN**: Clinical development programs meeting the regulatory standards for drug approval and labelling, Clinical trials data, Biomarkers, Patient-report outcomes, Quality management processes, etc.
- **Biomanufacturing 2020**: Analytical tools and methods needed during manufacturing of biopharmaceuticals, etc.
- **Unlock SLCs**: New screening methodologies for SLCs, etc.
- **Enhanced patient voice**: Good practices, Blueprint, Metrics, etc.
- **Autism**: European registry, Clinical trials outcome markers, Clinical data, etc.

# Ownership of results

## *Articles 26.1 & 26.2 IMI2 MGA*

- Results are owned by the beneficiary(ies) who generate(s) them
  - Upfront different allocation of ownership not provided for but possibility to per-agree on transfer between beneficiaries
    - solely owned results
    - jointly owned results for which beneficiaries can establish the respective contributions to the results before they are generated AND Beneficiaries know that it will be possible to separate the results for the purpose of applying, obtaining or maintaining their protection
- Possibility of transfer and licensing to affiliates / third parties subject to certain conditions

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# Protection of results

Mandatory for
beneficiaries receiving funding

**Common practice**

- lies with the owner(s) in adequate and effective manner ➡ relevant (national) legal provisions, action peculiarities, legitimate interests
- if valuable results left unprotected ➡ to be discussed within the consortium

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# Results and Access rights

- Grant of access rights to beneficiaries :
  - for action implementation (including to affiliated entities)
  - for research use of results
- Grant of access rights to third parties :
  - after completion of the action
  - for research use of results

# Snapshot of key concepts

Background identification

Start

**Implementation of the action**

End

Results

Access rights (rights of use)

Access rights (rights of use)

**Sideground**

Generated during the action but **outside its objectives** and not needed for implementation or research use

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# Access rights

# Access Rights

***Article 25.1. IMI2 MGA***

- Access rights = rights to use

- Written request mandatory under IMI2 (no «unless otherwise agreed» like in IMI1)

- Access rights are in principle not sub licensable but beneficiaries may agree in the consortium agreement to define certain situations where sublicense apply **=> Traceability**

- **Time limit to request access rights**
  - Different from IMI1 (no time limit)
  - No minimum/maximum
  - Consistent with particular project/results/background

# Access Rights - Purposes

## Research Use

- Use of results or background necessary to use the results for all purposes other than for completing the action or for direct exploitation
- The application of results (like an animal model or a biomarker) as a tool for research and clinical research in the discovery or development (as the case may be for commercialisation) of pharmaceutical products by for-profit institutions and organisations

## Direct Exploitation

- Development for commercialisation or to commercialise the results
- Commercialisation of such biomarker itself as a diagnostic kit would be direct exploitation

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# Access rights and third parties

- Only after the end of the action for research use purposes
- Possibility to exclude specific elements of background (only for existing background)

**Based on IMI1 experience**

- Time-limits to be agreed

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# Snapshot of access rights conditions

| Access rights granted by a beneficiary to/on | **Background** | **Results** | **Sideground** |
|---|---|---|---|
| **Beneficiaries for completion of the action** | **Royalty-free** | **Royalty-free** | N.A. |
| **Beneficiaries and affiliates for Research Use** | **Fair & reasonable conditions** (including royalty-free conditions) | **Fair & reasonable conditions** (including royalty-free conditions) | N.A. |
| **Third Parties for Research Use after the action** | **Appropriate conditions** | **Appropriate conditions** | N.A. |
| **Beneficiaries and affiliates or Third Parties for Direct Exploitation** | To be negotiated | To be negotiated | N.A. |

# Dissemination

# Dissemination of results

***Articles 29.1 and 29 2 of IMI2 MGA***

- Each beneficiary has the obligation to disseminate its own results

- Open access to scientific publications requirement

- Notification to IMI JU if dissemination without first protecting results (if generated with IMI funding) Except if (i) not possible, reasonable or justified, (ii) a lack of commercial exploitation possibilities; or (iii) a transfer to a third party in the EU which will protect.

Mandatory mention to IMI support & Partners' in-kind contribution in patent applications / all communications

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# Dissemination and Call 10 topics

- Scientific community
- Patient dedicated / oriented topics
- Regulators (guidelines, recommendations, etc.)
- HTA
- Policy makers

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# Legal basis and key documents

# Hierachy - IMI2 IP related documents

**H2020 Rules for Participation**

**Delegated Act-** derogation to the H2020 RfP

**IMI2 Model Grant Agreement** (IMI2 MGA)
Between IMI JU and Beneficiaries
Fixed template except for Annexes “Description of the Action” (DoA) and Budget table (-> project dependent)

**IMI2 Annotated Grant Agreement**
Guide for explaining IMI2 MGA

**IMI2 Consortium Agreement**
(Project Agreement in IMI1)
Between Beneficiaries. **Negotiable**.
Consistency with other legal instruments (incl. DoA)

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# IMI2 Legal Basis/Core Documents

- Regulation No. 1290/2013 (11th December 2013) laying down the rules for participation and dissemination in Horizon 2020 **(H2020 RfP)**
- Council Delegation Regulation (EU) No. 622/2014 (establishing a derogation from Regulation (EU) 1290/2013 **(Delegated Act)**
- Council Regulation (EU) No. 557/2014 (establishing the Innovative Medicines Initiative 2 Joint Undertaking).
- IMI2 Model Grant Agreement of February 2015 **(MGA)**
- IMI2 Annotated Grant Agreement ***(under finalization)***
- Template IMI2 Consortium Agreement developed by EFPIA ***(see EFPIA website)***

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# Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the **IMI2 model Grant Agreement**
- Before the signature of the grant agreement with the IMI Office
- **To be adapted to the specific needs of each IMI action!**

Make sure of close collaboration between science AND legal

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# Your contact points

## At the IMI Programme Office

- General queries: infodesk@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

## Local contacts

- IMI States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs

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# Thank you

## Please do not hesitate to raise your hand

www.imi.europa.eu

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