AI-powered signal detection in pharmacovigilance

IHI call 11 – topic 3

Nathalie Seigneuret
23.06.205 • Online

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Before we start…

- We are recording this webinar and it will be published on the IHI website.
- We will also publish the presentation slides.
- IHI call 11 was launched on 17.06.2025 and the final call texts and details of how to apply can be found at https://www.ihi.europa.eu/apply-funding/ihi-call-11
- Ask questions by using the chat function (bottom right on your screen)

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Today's webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 11 topic 3 presented by lead of the pre-identified industry consortium
  - Proposal submission & evaluation
  - Tips for writing a successful proposal

- **Will not cover**
  - rules and procedures

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Innovative Health Initiative

EU **partnership in health** between:

- the **European Union** represented by the European Commission

&

- **Healthcare industry associations:**
    - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
    - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
    - **EuropaBio** (biotechnology industry)
    - **MedTech Europe** (medical technology industry)

IHI's general objectives

- Turn health research and innovation into **real benefits for patients and society**

- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need

- Make Europe's health industries globally **competitive.**

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IHI projects are…

Created via open and competitive calls for proposals

Cross sectorial public private partnerships leveraging:

- Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTechEurope)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

- Public funding via European Commission (Horizon Europe)

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Strategic Research & Innovation Agenda
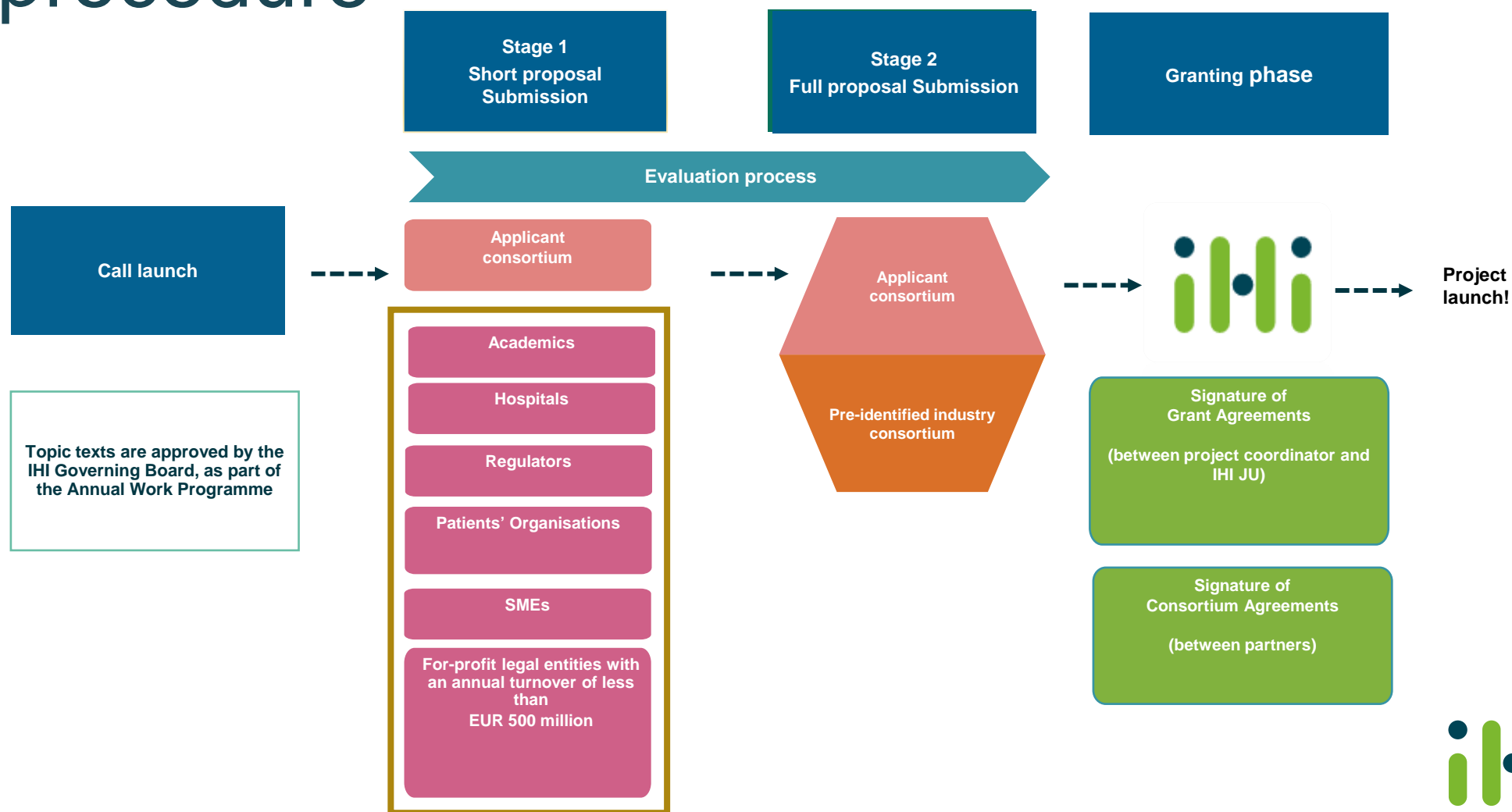
Focus

- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

Goal

- Lay foundations for development **of safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

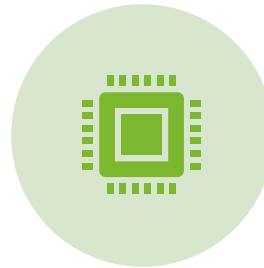> Research supported by IHI should remain at precompetitive level

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https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure

Stage 1
Short proposal Submission

Stage 2
Full proposal Submission

Granting phase

Evaluation process

Call launch

Topic texts are approved by the IHI Governing Board, as part of the Annual Work Programme

Applicant consortium

Academics

Hospitals

Regulators

Patients' Organisations

SMEs

For-profit legal entities with an annual turnover of less than EUR 500 million

Applicant consortium

Pre-identified industry consortium

Signature of Grant Agreements

(between project coordinator and IHI JU)

Signature of Consortium Agreements

(between partners)

Project launch!

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AI-powered Signal Detection in Pharmacovigilance

IHI call 11 – Topic 3

Juhaeri Juhaeri
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Challenge and opportunity

Spontaneous reporting systems (SRSs) have traditionally been used for detecting safety signals in pharmacovigilance but are limited by low accuracy and delays.

Other data sources could potentially be used for signal detection, including electronic health records (EHRs). FDA has started using EHRs for signal detection.

Application of AI in drug development is increasing, but its application in PV, especially signal detection, is limited.

AI offers a promising solution by improving the efficiency, accuracy, and timeliness of signal detection using DIVERSE and UNTAPPED data sources.

*Signal detection involves identifying potential relationships between drug exposure and outcomes that merit closer examination.

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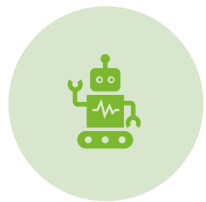initiative

Scope of the topic

Evaluate, select, optimize and test AI algorithms using disparate data sources for signal detection

Evaluate diverse data sources within a cohesive pharmacovigilance network

Develop AI algorithms for risk prediction

Create recommendations for implementing AI-powered systems in real-world scenarios

Develop recommendations for Human in the Loop (HITL) and Human on the Loop (HOTL) AI in pharmacovigilance

Develop templates and tools for practical implementation

Create training plans and education materials

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Expected outcomes

Evidence-based and practical guidance on AI use for signal detection and other PV applications

AI-powered algorithms for faster and more accurate signal detection

AI-powered algorithms for highly accurate risk prediction

Comprehensive list of data sources where AI methods could improve signal detection

Recommendations for implementing AI-powered systems in real-world scenarios

Tools and templates for practical implementation

Training guides and educational materials

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Expected Impact

Enhanced drug safety through improved speed and accuracy in identifying adverse drug reactions

Proactive risk management through improved assessment and prediction

Improved patient safety through earlier and more effective risk management

Faster and more informed decision-making through AI-driven insights

Increased efficiency through rapid processing of vast amounts of data

Streamlined processing by automating routine pharmacovigilance tasks

Support for future policies and regulations

Increased consistency in approaches used by industry, academia and regulators

Improved European competitiveness and contribution to European policies/initiatives

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Need for public-private, cross-sector collaboration

The successful integration of diverse data sources and development of advanced AI algorithms necessitate collaborative effort
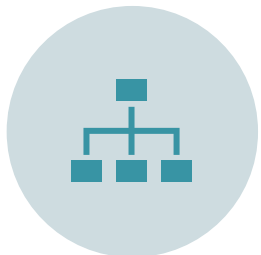
Multi-disciplinary collaboration needed between **data science, AI, pharmacovigilance, RWD/RWE, regulatory affairs, and clinical research**

Regulatory science and oversight require active involvement of **regulators** to foster shared confidence in AI tools

Public-private partnership is ideal to bring all stakeholders (**patients, academics, industry, regulators**) together

Large-scale projects require significant resources and infrastructure that individual organizations might find challenging to provide alone

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Expected contributions of the industry consortium

- AI and machine Learning specialists (Data Scientists, NLP experts)

- Pharmacovigilance experts (Pharmacologists, Regulatory experts)

- RWD/RWE experts (Pharmaco-epidemiologists)

- Ethics and data protection specialists

- Healthcare data experts (Epidemiologists, Biostatisticians)

- IT and data management professionals (Database administrators, Software engineers)

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Expected contributions of the applicants

Expertise and resources expected to be brought into the project

Expertise and resources needed:
- Pharmacovigilance, epidemiology, RWD/RWE, data science, AI, biostatistics
- Risk modeling, assessment and management
- Data privacy and protection, ethics
- Experience in engaging with patients
- Regulatory and compliance framework SOPs
- Ethics and project management expertise

Resources to provide:
- Technological infrastructure (High-performance computing, Data storage solutions)
- Access to data sources in a GDPR-compliant manner (EHRs, Spontaneous Reporting Systems, Medical Literature, etc.)

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Key Facts

👥	**Consortium**	Pre-identified industry consortium: **17 companies** – **Sanofi** as Industry Lead
🪙	**Budget ~ 20 Million EUR in total**	**11 418 645 EUR** industry in-kind commitments identified **8 906 000 EUR** maximum financial contribution from the IHI JU
⏱	**Duration**	The indicative duration of the action is 60 months

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Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu

Proposal submission & evaluation

Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.

- **Part B** of the proposal is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**

- **Annex:**
  - Participant type

Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
  - Soundness of the proposed methodology
- **Impact**
  - Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the outline of the work plan
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

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Tips for applicants

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - www.ihi.europa.eu/apply-funding/open-calls

- Form your consortium **early**
  - Already think "public-private partnership"

- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria

- Consider & plan for the potential **regulatory impact** of results (see also our guide)

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Finding project partners

You'll need to build or join a consortium!

- Use EU Funding & Tenders portal **partner search tool:**
  - https://europa.eu/!QU87Nx

- Get in touch with your **IHI national contact point**:
  - https://europa.eu/!D7jyMy

- Network on social media:
  - https://bsky.app/profile/ihieurope.bsky.social
  - be.linkedin.com/company/innovative-health-initiative

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Eligibility for Funding: UK, Canada, Switzerland, South Korea

In IHI Call 11, legal entities from the following countries are Eligible/Not Eligible
to receive funding as follows:

Country	Call 11, Topic 01	Call 11, Topics 02 - 05
United Kingdom ('UK')	Eligible to receive funding	Not Eligible to receive funding
Canada ('CA')	Eligible to receive funding	Not Eligible to receive funding
Switzerland ('CH')	Not Eligible to receive funding	
South Korea ('KR')	Not Eligible to receive funding	

Alternative Funding: legal entities from UK, CA, CH, and KR may be able to receive funding from their own governments, Potential applicants should contact their National Contact Point ('NCP') or relevant representative. IHI JU takes no role or responsibility in the application for, or granting of, such funding.

UK applicants: Are requested to contact the UK National Contact Point Ms Jo Frost (ncp-health@iuk.ukri.org) as soon as possible to register for updates, and for advice and assistance regarding UK participation in IHI Call 11.

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Thank you for your attention

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