Maximising the potential of synthetic data generation in healthcare applications

Update 04-07-2023: Slides 21 & 22 added for clarification

IHI call 5 – topic 4

Colm CARROLL
29.06.2023

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Before we start…

- All information regarding future IHI call topics is indicative and subject to change. Final information about future IHI calls will be communicated after approval by the IHI Governing Board.
- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.

Before we start…

Questions

- Please use the **‘Join the discussion’ function** at the bottom right of the screen to ask questions.

Today’s webinar

Will cover:

- Introduction to IHI programme
- IHI Call Topic:
  - Challenge, need for public-private collaborative research
  - Scope, outcomes & impacts, budget
- Proposal preparation tips, matchmaking & participant pitches

Will not cover rules & procedures or budgets

- These webinars are on the IHI website
  - www.ihi.europa.eu/news-events/events/ihi-call-days-calls-4-5

Innovative Health Initiative

Public private partnership 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)

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COCIR Advancing Healthcare | efpia | EuropaBio The European Association for Bioindustries | MedTech Europe from diagnosis to cure | Vaccines Europe | Co-funded by the European Union

IHI´s General objectives

Through **cross sectoral, pre-competitive** collaboration:

- 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.**

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

IHI Funding model

As a **public private partnership,** IHI's projects are funded by:

- EU **cash contributions**
  - Primarily supporting universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies.*
- IHI **industry associations** & **contributing partners**
  - Must **provide at least 45% of total project eligible costs**, usually via researchers participating in the project

* Large companies can also receive EU funds

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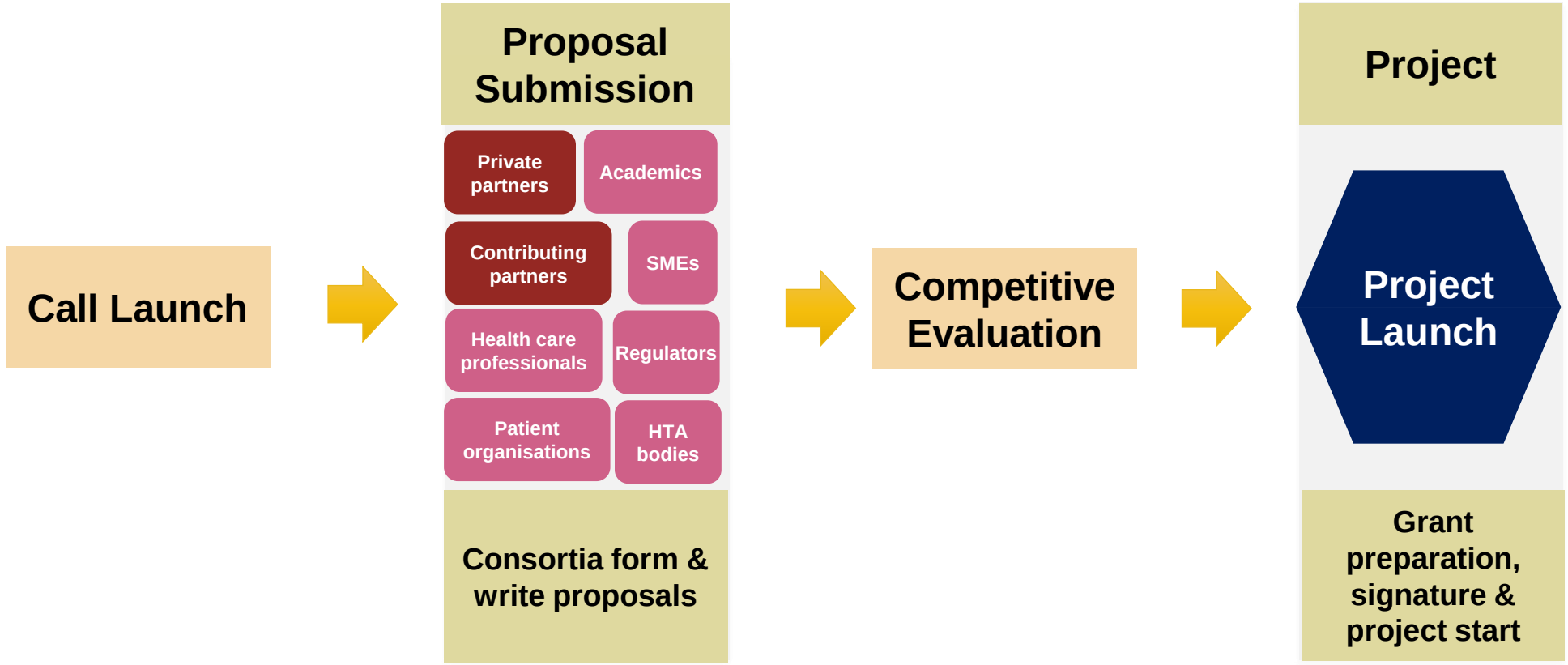
How IHI works: Single-stage procedure



Maximising the potential of synthetic data generation in healthcare applications

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The challenge

- Healthcare research using **individual patient data is often constrained.**
- Synthetic health data can reduce these concerns, leading to more rapid development of **reliable data-driven methods** including diagnostic, precision medicine, decision support and patient monitoring tools.
- However, while many synthetic data generation (SDG) methods are currently available, it is **not always clear which method is best** for which use case, and SDG methods for some types of data are **still immature.**

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Need for public-private, cross-sector collaboration

- Development and validation of synthetic data generation methods and tools for data-driven applications requires multidisciplinary collaboration across private and public entities including:
  - Public and private data owners
  - Healthcare solution developers
  - Synthetic data experts.

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Scope of the topic (1/2)

- Assemble a **cross-sectoral public-private consortium** including synthetic data experts, public and private data owners, and healthcare solution developers.
- Using high-quality public and private datasets, **develop/ further develop and validate reliable SDG methods** for relevant healthcare use cases.
- The use cases to be explored should:
  - Ensure the **broad applicability** of the SDG methods developed
  - Include **data types that are not currently adequately addressed**
  - Include methods to generate **fully synthetic datasets** not containing any real data; **hybrid datasets**, i.e., combination of data derived from both real and synthetic data; and **synthetically-augmented datasets**.
  - Pay particular **attention to bias**, both in source data and in the SDG methods.

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Scope of the topic (2/2)

- **Validate** the synthetic data generation methods applied in the project using source data.
- Demonstrate the **quality and applicability** of the synthetic data generated in the project through the development of **relevant models.**
- **Encourage the uptake of the results** of the project through a strong communication and outreach plan.

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Expected outcomes

- Researchers have a better understanding of the applicability and suitability of **different synthetic data generation methods** in specific use cases.
- Researchers have better **tools, including open access when relevant**, to create and share pools of synthetic patient data for research.
- Researchers have access to **relevant, high quality synthetic datasets**.
- Healthcare providers and industry have a wider range of **performant AI-based and other data-driven tools** to support diagnostics, personalised treatment decision-making and prediction of health outcomes.

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Expected impacts

- Wider **availability of interoperable, synthetic da**ta facilitating research and the development of **integrated products and services** to benefit patients.
- Improved insight into **real-life behaviour and challenges of patients** with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies.
- **Advanced analytics/artificial intelligence tools** supporting health research and innovation.

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Dissemination, exploitation & communication

- Think of a **project as a catalyst** for what comes afterwards
- **Reserve budget** for effective communication, consider an early **business/exploitation plan**
- In particular:
  - Encourage the **uptake of the results** of the project
  - **Allocate resources** to **explore synergies** with other relevant initiatives and projects, including the European Health Data Space (EHDS)
  - If applicable, include elements in line with the Availability, Accessibility and Affordability (3A) provisions

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Budget

Expected Project Budget 20-24M EUR

Budget

Expected Project Budget 20-24M EUR

IHI financial contribution:
10 - 12M EUR

Budget

Expected Project Budget
20-24M EUR

IHI financial contribution:
10 - 12M EUR

Industry & CPs contribution:
10 - 12M EUR*

*at least 45% of the project budget must be covered by contributions from project participants

Budget

Expected Project Budget 20-24M EUR

IHI financial contribution:
10 - 12M EUR

Industry & CPs contribution:
10 - 12M EUR*

Total available IHI financial contribution for this topic: 24M EUR

*at least 45% of the project budget must be covered by contributions from project participants

Simplified budget example

Single-stage call proposals

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	15 million	100%	15 million	0
Private members & contributing partners (requested funding = 0)	15 million	100%	0	15 million
Private members & contributing partners ('Hybrid')	10 million	100%	5 million	5 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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Simplified budget example

<u>Two-stage</u> call Full proposal

<u>Not eligible for funding</u> : pre-identified private members and contributing partners
Large companies with annual turnover > 500 M

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Proposal Submission & Evaluation

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Proposal Template: Parts A, B & Annexes

- **Part A** is **administrative & researcher data** that is entered in webforms.

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

- **Annexes:**
  - Participant type
  - Budget details, IKAA table (if relevant)
  - Coordinator declaration
  - Clinical studies template*

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*If no clinical studies included in the proposal, please upload a statement to confirm that no clinical studies is foreseen.

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, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.
- **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.
  - Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

Tips for applicants

Tips for applicants (1/2)

- **Read all the call-relevant material, especially the topic text**

https://www.ihi.europa.eu/apply-funding/future-opportunities

- Watch the ***"Rules and Procedures"*** & ***"preparing the financial part of the proposal"*** webinars

Tips for applicants (2/2)

- **Form your consortium early**
  - Always think “public-private partnership“
  - Include partners bringing in-kind contributions

- Provide **all information requested** in call text & proposal template
- Allow the evaluation experts to **easily assess your proposal against the evaluation criteria**

- Consider & plan for the **potential regulatory impact** of results

Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call days participants:**
- https://ihi-call-days.ihi.b2match.io/
- 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:
  - www.twitter.com/IHIEurope
  - be.linkedin.com/company/innovative-health-initiative

How to book your meetings via the B2Match platform

Book your meetings in 4 easy steps

1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: https://europa.eu/!FkjV9n

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Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

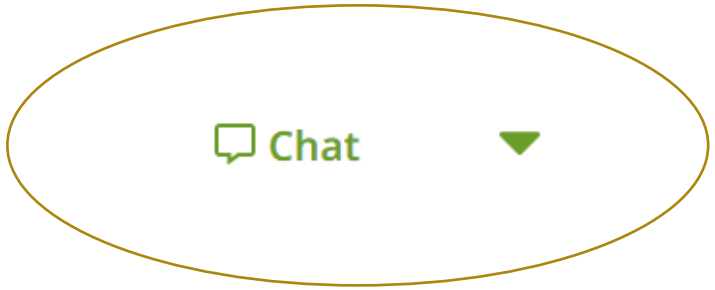
MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Questions time

If you want to ask a question please use the chat function on the right corner of your screen



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Additional Slides

Simplified budget example

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#IHICallDays

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Call 5

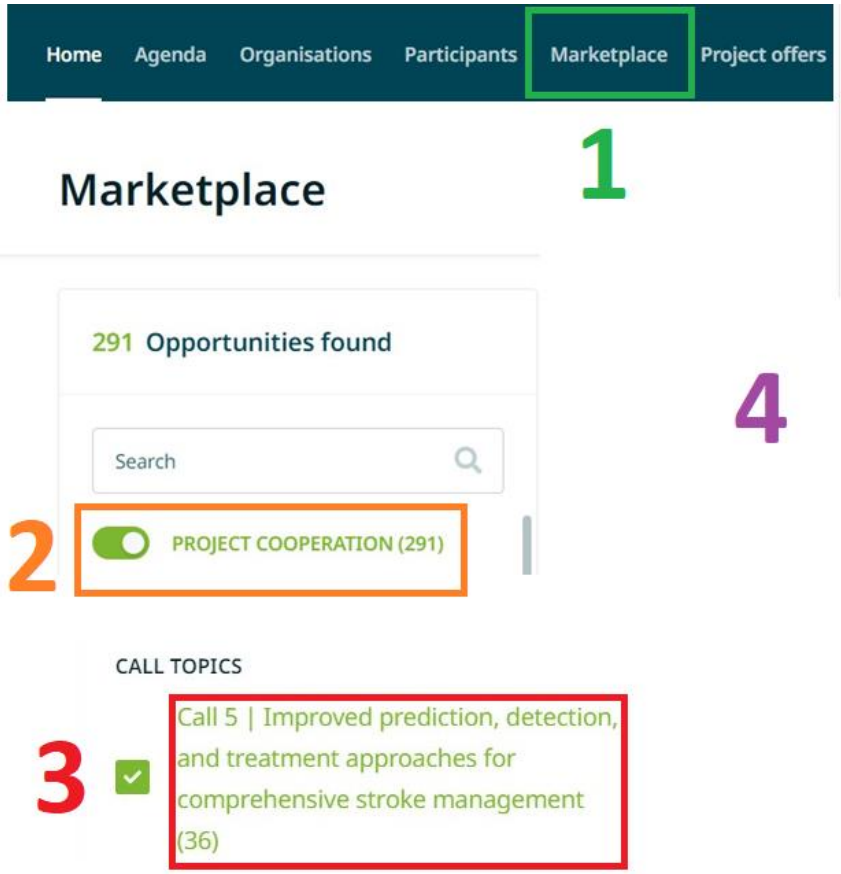
26 June	15:00-16:30	IHI rules & procedures
27 June	10:00-12:10	Non-animal approaches for health technologies
27 June	14:00-16:10	Theranostics solutions
28 June	14:00-16:10	Stroke management
29 June	10:00-12:10	Synthetic data generation
29 June	14:00-15:30	The financial part of the proposal

Online event

Register now

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe Co-funded by the European Union

Marketplace



4

PROJECT COOPERATION — Updated on June 21, 2023

EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION — Updated on June 21, 2023

Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

PROJECT COOPERATION — Updated on June 21, 2023

Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?

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We are taking now a 5 minutes break

Pitching Session

Call 5 – topic 4 – Synthetic data generation – 29 June 2023

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Saurav Kumar	Baidya	Senior Project Leader, Public Private Partnerships	Philips	Innovative synthetic data generation to train artifact-free diverse imaging and non-imaging healthcare algorithms
2	Emad	Yaghmaei	Senior consultant	YAGHMA B.V.	Trustworthy and neutral assessment of the impact of AI projects.
3	Oleg	Agafonov	Senior Researcher	DNV	Creating Trust in Synthetic Data for Healthcare
4	Vajira	Thambawita	Research Scientist	Simula Metropolitan Center for Digital Engineering	DeepSynthBody: Machine-learning framework to address data insufficiency in the medical field
5	Liam	Childs	Data Science Unit Lead	Paul Ehrlich Institute	Synthetic data: Leveraging Synthetic Data for Pharmacovigilance and Drug Safety

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iSyData

cool data for cool things

Innovative **sy**nthetic **data** generation to train artifact-free diverse imaging and non-imaging healthcare algorithms

Johan van den Brink, Saurav Kumar Baidya,

Peter Zandbergen

Philips Medical Systems Nederland B.V.

saurav.baidya@philips.com

peter.zandbergen@philips.com

Call 5, Topic number 4

COCIR Advancing Healthcare

efpia

EuropaBio

MedTech Europe from diagnosis to cure

Vaccines Europe

iSyData

Challenges and objectives

Currently, training of diverse imaging and non-imaging algorithms in the healthcare data space faces challenges of **non-availability of large training datasets with ground truth, undocumented variability of instrumentation and procedures, and lack of validation, standardization, accuracy and efficiency**.

We aim to address this challenge by providing tools for generation of persistent and transient (“in-model”) synthetic data, including automation of validated data labelling, curation and validation. This approach will be supported by a modular framework of state-of-the-art technologies with the aim to reduce development time, energy consumption of storage and model training, and facilitate regulatory submissions through (inherent) generalizability and trustworthiness as demonstrated from multiple use cases.

iSyData

Technical goals

- High-resolution spatio-temporal data generation models for simulation of realistic images, physiological signals and biomarkers of humans and animals, and realistic Electronic Health Records
- Development and validation of (AI) models to simulate and generate transient or persistent synthetic data, including improved workflows
- Enrichment of synthetic data through augmentation of real-world and personalized data, generative AI and auxiliary sensor systems
- Modular technology framework with possibility to extend to cloud/edge infrastructure
- Optimization and validation of reconstruction, segmentation, biomarker analysis algorithms, QA/QC tests and real-time Out-of-Distribution / domain shift detection
- Tooling for consistency & correlation check, validation & interoperability standardization
- Building of public image databases. Links to different data ecosystems and data spaces

iSyData

Economical impact

- Assurance of trustworthiness and generalization of AI-based analysis in healthcare
- Public image databases of better, exhaustive and large set of data with connectivity to other data ecosystems and data spaces
- Significant reduction in development time, development cost (real data very expensive and difficult to collect), lifecycle maintenance and significant improvement in quality of AI algorithms and associated workflows with much better and customized data for the purpose.
- Growth, including synthetic data generation companies (SMEs)

Expected duration / budget

- Duration: 54 months
- Budget: 15 M€ funding

iSyData

Partners (Tentative list)

- Large Industry: Philips Medical Systems (Netherlands and Germany)
- Image biomarker companies (multiple SMEs)
- Research and Technology Organizations & Academia

- We seek interested big industry organizations from pharma and MedTech with a focus on lifestyle monitoring, lab data, EHR and pathology

Pitching Session

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IHI Call Days | Call 5

Topic name

Presentation title

Contact person name: Emad Yaghmaei
Organisation: YAGHMA B.V.
E-mail: ey@yaghma.nl
Link to:

- Marketplace opportunity
- Participant profile

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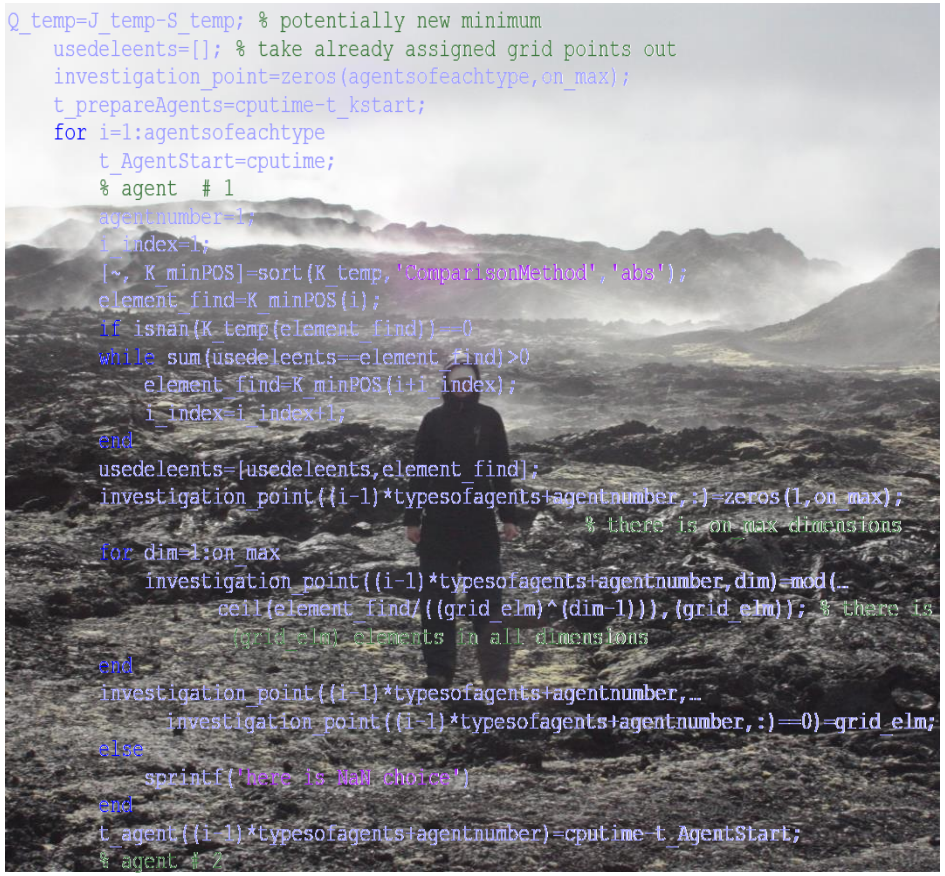
YAGHMA AI Impact Assessment

As artificial intelligence (AI) is getting widely introduced, concerns about its impact on society and environment arise.

To address the concerns of end-users, policy makers and other stakeholders, YAGHMA provides trustworthy and neutral assessment of the impact of AI projects.



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We help Digital Health projects develop and deploy trustworthy AI. Our tool guide organizations that procure and/or deploy AI solutions to choose AI solutions that are more beneficial to stakeholders and society.

- Assess privacy, transparency, bias, accountability, explainability of Digital Health
- Work on methods and tools for identify, implement and verify trustworthiness issues (e.g., explainability, bias and privacy) for multimodal AI based decision support for health care applications.
- enable companies/organisations to manage and prioritize the impact of their AI project through consultation and access to an easy to use, insightful, and standardized framework.
- Support companies'/organisations' internalisation of impact awareness through consultancy services, workshops and a set of comprehensive indicators/disclosures which can be included in the company's/organization's practices and operational strategy.

Current performance and future improvements

YAGHMA's AI impact assessment tool helps organisations:

- **Assess** – Assess their AI project's current environmental, social, ethical, legal, and governance impact performance.
- **Compare** – Compare internal projects to achieve an objective rating of the AI project's current performance. Compare with external projects through benchmark information.
- **Improve** – Improve the impact of their ongoing and future AI projects by setting and tracking performance goals using customized improvement reports, best practice examples and resource guides, and discussions on prioritisation and implementation.

How YAGHMA helps AI Health projects

Materiality Analysis

Contextualise the impact assessment of specific projects. Ensure consistency and completeness of trustworthy AI disclosure with data-backed insights into 200+ external impact factors.

AI Impact Assessment

Conduct a dynamic AI impact assessment and update AI project with deeper insights into environmental, social, ethical, legal, and governance impact performance, risks and opportunities and peer benchmarks.

AI Project Oversight/AI Auditing

Generate quarterly monitoring updates showcasing how the impact performance evolve, how the AI project' peers and others assess their impact performance, address emerging risks, and how related AI policies develop worldwide.

AI Project Strategy

Spotlight external impacts, risks and opportunities specific to the AI project, and identify potential gaps between the project' impact performance and trustworthy AI disclosures and AI regulations.

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IHI Call Days | Call 5

- Maximising the potential of synthetic data generation in healthcare applications

Creating Trust in Synthetic Data for Healthcare

Contact person name: Serena Marshall & Oleg Agafonov

Organisation: DNV

E-mail: Oleg.Agafonov@dnv.com, Serena.Elizabeth.Marshall@dnv.com

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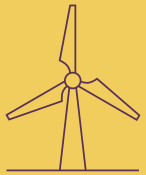
DNV - An independent assurance and risk management company

157	~12,000	100+	5% R&D
years	employees	countries	of annual revenue

Ship and offshore classification and advisory

Energy advisory, certification, verification, inspection and monitoring



Management system certification, supply chain and product assurance

Software, platforms and digital solutions

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DNV’s roles in Healthcare

Quality and risk management in technology adoption

Data sharing, harmonization, and governance

EU MDR Notified Body

Management System Certification

Cybersecurity

DNV Imatis

Solutions for the digital health sector

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Challenges and objectives

- **Main objectives of the proposal and how they address the outcomes and impacts of the topic**.

Synthetic data (SD) can help to overcome data privacy challenges, associated data-sharing limitations, and data scarcity in healthcare. We propose to create trust in SD by developing an SD assurance scheme - a systematic approach that involves a set of procedures and standards designed to instill confidence by ensuring that both the SD generation process and resulting SD meets specific requirements and expectations

- **What problem are you trying to solve?**

Despite the high potential, there is limited trust and hence use of SD in healthcare as well as in other industries.

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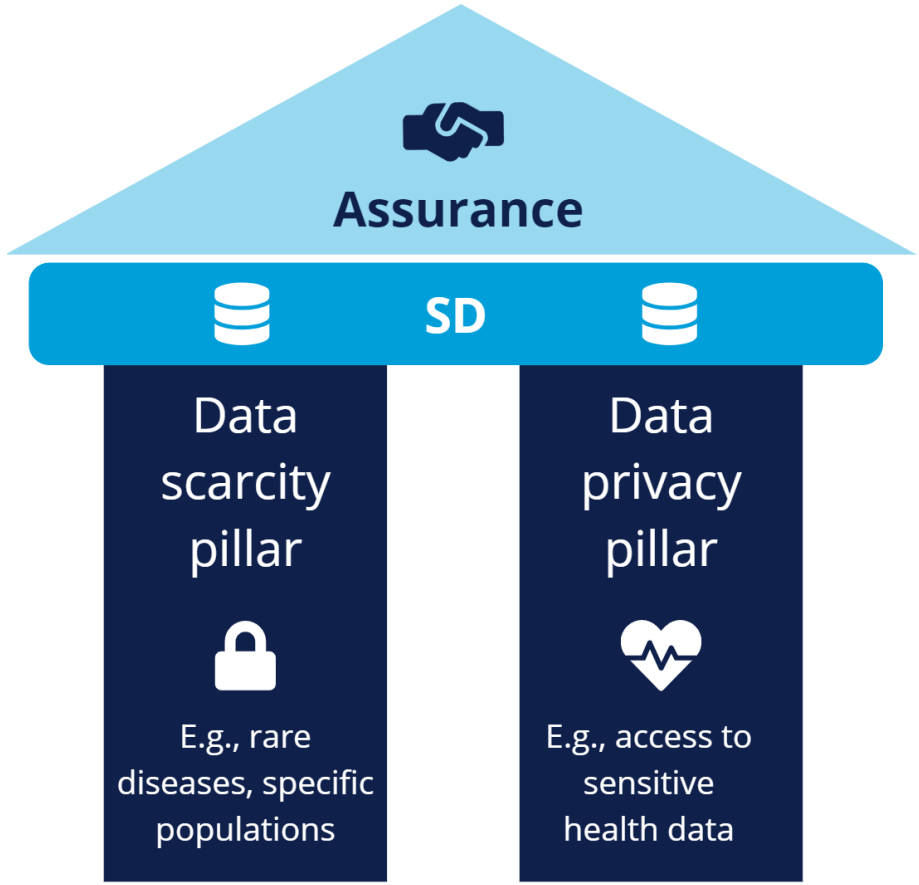
Main activities

We aim to investigate **which methods can create trust in SD for healthcare?**

We need to identify robust quality metrics to ascertain the representativeness, reliability and utility of SD that will comprise an SD assurance approach.



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Expertise and resources offered

- DNV has a vast experience in **risk management** and **quality assurance**. DNV's expertise in standards and assurance can provide robust frameworks to guide the development and evaluation of SD. In the healthcare sector, DNV has a profound understanding of the **regulatory landscape** and a history of collaboration with healthcare research institutions. Furthermore, DNV has an ongoing **industrial PhD project** in collaboration with Oslo University and Oslo University Hospital on **use of SD for validation of AI-based tools in healthcare**.

- DNV has an ongoing collaboration with the Cancer Registry of Norway (CRN), which is renowned for its nation-wide high-quality registries of cancer patients with data going back 70 years. With its rigorous data collection, standardized data curation and coding protocols, and detailed information, the CRN stands as a valuable resource for cancer research. This, coupled with their deep understanding of the cancer pathogenesis and analytic competence, makes CRN an invaluable partner for a project on SD.

Expertise requested

- We are looking to join a consortium, which has a need for assurance mechanisms to support scaled up use of SD.

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IHI Call Days | Call 5

- Maximising the potential of synthetic data generation in healthcare applications

DeepSynthBody: Machine-learning framework to address data insufficiency in the medical field

Contact person name: Vajira Thambawita (Research Scientist)

Organisation: Simula Metropolitan Center for Digital Engineering (SimulaMet)

E-mail: vajira@simula.no

Marketplace:

Participant profile:

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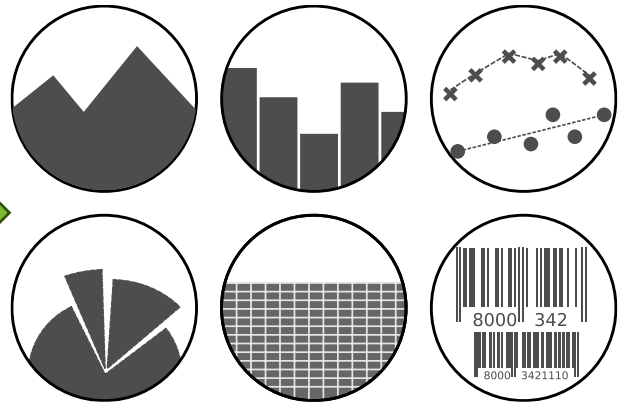
Challenges and objectives

Healthcare + AI



Data is the KEY

- Privacy Issues
- Rare True Positive cases
- Timely and costly data annotations
- Generalizability issues with biased real-data

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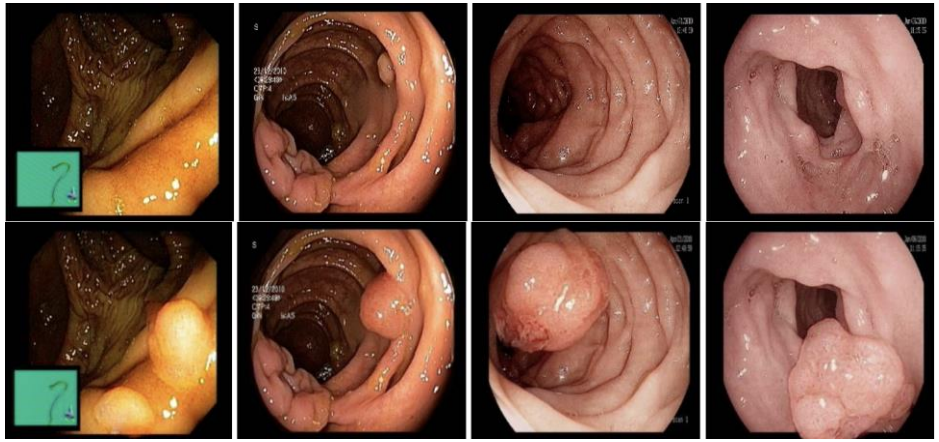
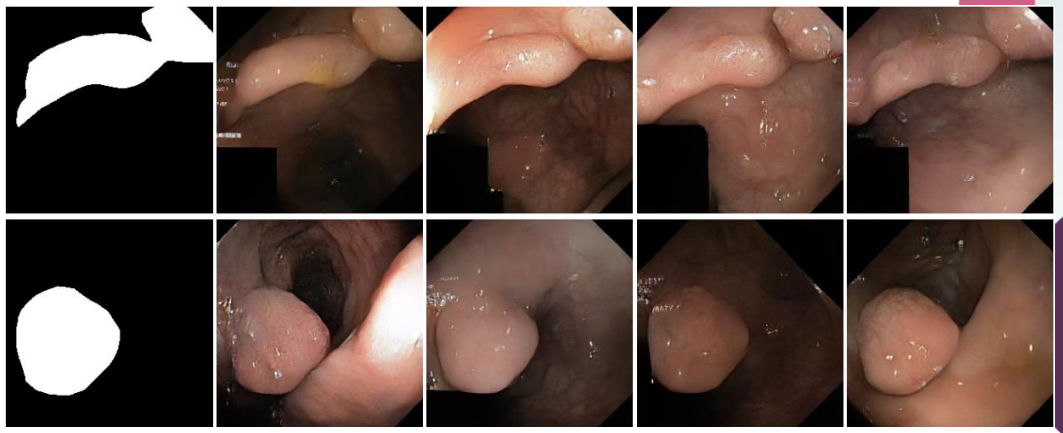
Challenges and objectives

Privacy Issues

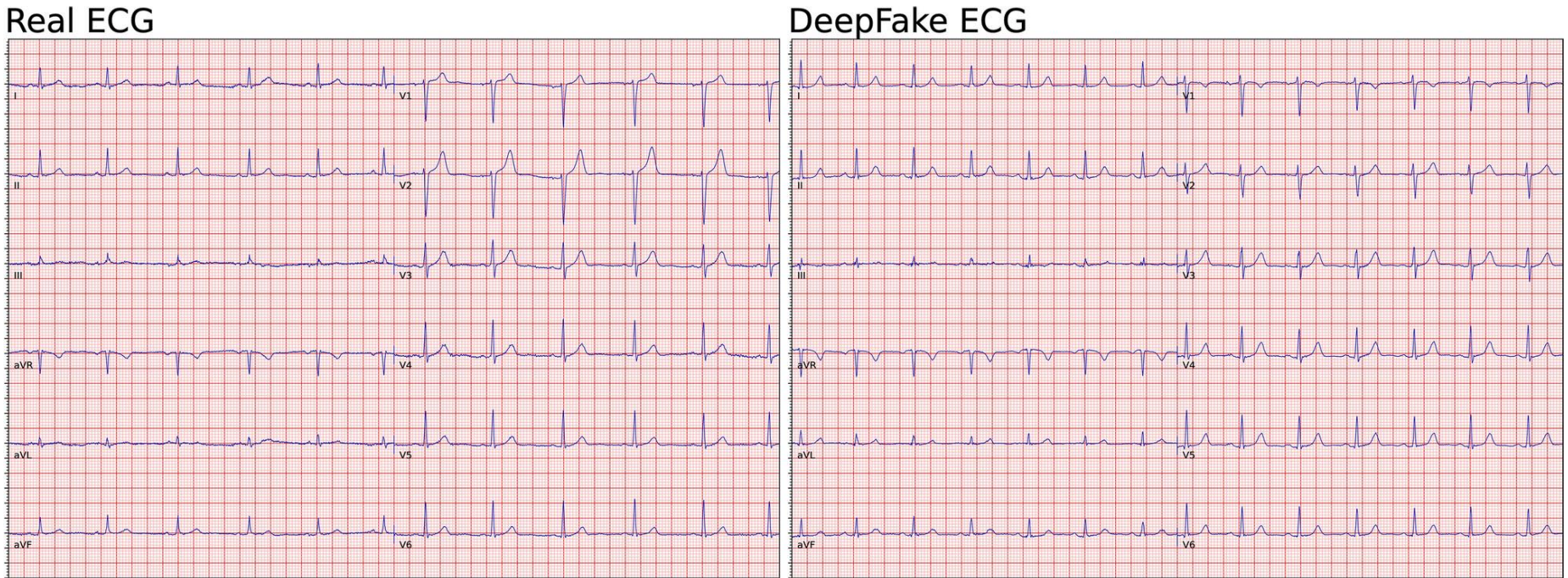
Rare True Positive cases





Timely and costly data annotations

Generalizability issues with biased real-data



Main activities

- Collecting different type of real medical datasets
- Research and implement deep generative models with different type of data (Signals, Images, Videos, fMRI etc.)
- Implementation of user friendly platform to generate synthetic data and publish pre-generated datasets (implementation of the biggest synthetic medical data repository)
- Evaluate and benchmark synthetic datasets using other ML models (classification, detection, segmentation etc.)

Medical Hugging Face?

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Expertise and resources offered

- Simula + **SimulaMet** + SimulaUiB

Scientific Computing

Cryptograpy

Software Engineering

Machine Learning

Communication Systems

Expertise requested

Research Institutes	Hospitals	Companies	Other?
• AI/ML • Software/ UI • Data security • Systems Engineering	• Data access • Clinical/medical experts • Data validation	• Software developments • Data handling, storage • System developments	• ??

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Pitching Session

Call 5 – topic 4 – Synthetic data generation – 29 June 2023

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Saurav Kumar	Baidya	Senior Project Leader, Public Private Partnerships	Philips	Innovative synthetic data generation to train artifact-free diverse imaging and non-imaging healthcare algorithms
2	Emad	Yaghmaei	Senior consultant	YAGHMA B.V.	Trustworthy and neutral assessment of the impact of AI projects.
3	Oleg	Agafonov	Senior Researcher	DNV	Creating Trust in Synthetic Data for Healthcare
4	Vajira	Thambawita	Research Scientist	Simula Metropolitan Center for Digital Engineering	DeepSynthBody: Machine-learning framework to address data insufficiency in the medical field
5	Liam	Childs	Data Science Unit Lead	Paul Ehrlich Institute	Synthetic data: Leveraging Synthetic Data for Pharmacovigilance and Drug Safety

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IHI Call Days | Call 5

Synthetic data
Leveraging Synthetic Data for Pharmacovigilance and Drug Safety

Contact person name: Liam Childs

Organisation: Paul Ehrlich Institute

E-mail: liam.childs@pei.de

Link to:

- UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjcwOTM2
- https://ihi-call-days.ihi.b2match.io/participations/265573

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Challenges and objectives

- We seek to develop signal detection algorithms for identifying adverse drug reactions under differing scenarios such as:
  - reactions reported after the change in manufacturing process
  - reactions confounded by seasonal variation,
  - reactions cause by the use of multiple drugs.
- We expect to improve the algorithms used to detect rare adverse reactions using datasets that closely imitate real world events.

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Main activities

- Generating synthetic data from real world pharmacovigilance datasets.
- Simulating multiple scenarios (e.g. ADR after manufacturing change, seasonal reactions as confounders, multi-product ADR).
- Detecting signals in synthetic ADR datasets.

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Expertise and resources offered

- Large dataset that can be used to synthesise ADR datasets with realistic distributions of drugs and reactions.
- Regulatory expertise
- Domain expertise in drug safety evaluation
- Regulatory perspective

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Expertise requested

- Synthetic data experts
- Statisticians and signal detection experts

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Thank you for your attention

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EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

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