EIT Health INNOV+DOCTOR

Start-ups meet Doctors: Artificial intelligence

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Executive Summary

EIT Health Spain is leading 'INNOV+DOCTOR – a strategic initiative which aims to promote clinical innovation across Europe. During 2020 we have worked hard to introduce new objectives, and to internationalise existing ones, building on the foundations laid down in Spain during 2019. One such objective - 'Start-ups meet Doctors' – saw us deliver two roundtable sessions with healthcare professionals and entrepreneurs, delving into two specific themes. On 27th October our participants focused on neuro-rehabilitation; and on 25th November we explored the field of Artificial Intelligence.

This report captures the key themes from the second session and sets out our conclusions and recommendations towards further innovation in Artificial Intelligence. We also share some examples of good practice towards early dissemination of our findings.

Our vision for this series of roundtables is that we can further promote the latest and emerging clinical innovations in different areas of healthcare; highlight the opportunities for joint working towards delivering truly innovative solutions for patients; and start a European-wide conversation on the benefits of encouraging and supporting thematically focused conversations between healthcare professionals and entrepreneurs towards high value care.

Our sincere thanks to those who participated, and contributed their valuable time and knowledge.

Cristina Bescos

Managing Director, EIT Health Spain

Introduction

Clinicians and doctors are well-placed to identify healthcare needs and innovative solutions; and start-up companies and entrepreneurs are fundamental in developing these solutions. There is a need to further encourage, facilitate and support these partnerships and wider ecosystems towards true innovation in the design and delivery of high value care.

In 2019, EIT Health Spain launched a new initiative called INNOV+DOCTOR to drive and promote clinical innovation in healthcare for the benefit of patients. INNOV+DOCTOR works by:

- Facilitating focused discussions between healthcare professionals and start-up companies to explore some of the key challenges and opportunities in clinical innovation
- Supporting healthcare professionals and entrepreneurs to access the market with their innovative ideas and solutions
- Growing the European community of Clinical Ambassadors to facilitate the sharing of success stories, good practices and innovation pathways, promoting healthcare professionals as innovators and entrepreneurs
- Collaborating with EU medical societies to operationalise their innovation, acceleration and educational activities.

A key activity of INNOV+DOCTOR is to introduce entrepreneurs from start-up companies to leading healthcare professionals, to facilitate discussions around the challenges and potential solutions for clinical innovation in different areas of healthcare. 'Start-ups meet Doctors' launched in October 2020 with the first session focusing on neurorehabilitation.

Objectives:

- Gaining an increased appreciation of how collaboration can benefit patients, start-ups and healthcare professionals
- Understanding the emerging challenge propositions for start-ups in the healthcare system
- Identifying good practice and success stories to help spread the importance of clinical innovation.

Four entrepreneurs and four clinicians were invited to join the AI discussion, which was hosted and moderated by EIT Health Spain via Zoom on 25th November 2020. It took place against the backdrop of the COVID-19 pandemic - a driver for disruptive

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innovation in itself - with emphasis on data access, quality and trust; and implications for the workforce.

The current situation: State of the art in artificial intelligence

> *"Artificial intelligence (AI) has the potential to transform how care is delivered. It can support improvements in care outcomes, patient experience and access to healthcare services. It can increase productivity and the efficiency of care delivery and allow healthcare systems to provide more and better care to more people. AI can help improve the experience of healthcare practitioners, enabling them to spend more time in direct patient care and reducing burnout. Finally, it can support the faster delivery of care, mainly by accelerating diagnosis time, and help healthcare systems manage population health more proactively, allocating resources to where they can have the largest impact".*

- EIT Health and McKinsey, 2020[i]

Prof Felipe Atienza set the scene with a *'State of the Art'* presentation. This was delivered from **the perspective of AI in cardiovascular medicine** including an overview of different AI systems; examples of important research findings; an introduction to an EIT Health project using AI towards patient stratification; and the main challenges associated with improving the clinical AI pathway. Prof Atienza provided a detailed technical introduction into AI which is available as an Appendix.

Research findings – examples

Professor Atienza shared some AI initiatives to stimulate debate around the table. These are examples only, and not intended as an exhaustive list.

In a Spanish study on heart failure mortality, different models were compared for their ability to predict a survival or death outcome following the patient's admission to hospital with heart failure. Researchers analysed two different systems: a classical logistic moderation model, and a neuro network model – both using the same clinical data from the patient's history. Results showed that sensibility, specificity, accuracy and the resulting ROC curve were significantly better in the neuro network model[ii,iii].

In a study by the Mayo Clinic, 12-lead electrocardiogram reports were analysed by AI to identify characteristics that could predict Left Ventricular (LV) heart failure. The predictive value of the electrocardiogram analysis was high, with an ROC curve of 0.93, being able to accurately identify patients likely to develop LV heart failure over a 15-year follow-up period.

Similarly, electrocardiograms can help with discrimination. By introducing the electrocardiogram and the data from it as input nodes, the AI system is able to produce output nodes which represent the patient's cardiac rhythm.[iv] Convolutional neuro networks have shown that AI systems are able to classify - with good statistical accuracy – the patient's cardiac rhythmic state[v].

Moreover, AI ECG analysis can also be used to predict whether the patient will have Atrial Fibrillation (AF) in the future. At a study carried out at the Mayo Clinic between 1993 and 2017, an AI-enabled ECG was able to accurately (ROC 0.87) identify those patients at risk of developing AF in the future, by analysing the presence of AF signatures during normal sinus rhythm.[vi]

Another approach of AI that can be applied to cardiovascular medicine is the field of (Magnetic Resonance Imaging) (MRI) In this case, obtaining the segmentation of the atria manually can be very time consuming (up to 8 hours) and is prone to errors. However, by applying the same data to a neuro network, it is possible to obtain these segmentation images in as little as 10 seconds)[vii]. To summarise, different algorithms are available depending on the characteristics of the data, the number of cases to be used, and the types of data to be applied. However, when the data approaches high numbers (>1000), the complexity of the images is very high, and so the neuro network would be the most eligible algorithm to apply.

The pathway to clinical AI involves a number of challenges.

Pathway → Development of AI tools from single site → Retrospective multi-site → Prospective evaluation → Clinical deployment

Challenges:

- expanding the methodology to handle larger sets of data (e.g.: genomics, histology, multi-omics, drug discovery)
- harmonisation, appropriate data and labelling (e.g.: outcomes, raw images, telemetry and device signals) for analytical use
- retrospective, multi-site validation of single centre clinical trials
- expanding and translating knowledge to the overall clinical workforce for electronic medical record (EMR) integration and issues around data access and privacy
- better understanding of the reimbursement landscape for AI solutions[viii].

“Custom-made” solutions

Prof Atienza’s introduction encouraged a discussion about the importance of collaboration and multi-disciplinary teams including engineers, clinicians, physicians, data experts, and health economists, among many professionals to lead this paradigm shift. These solutions are, however, ‘homemade’ for a specific hospital or primary care setting; and this creates hurdles for offering the solution to another hospital or laboratory, as the framework is not always adaptable.

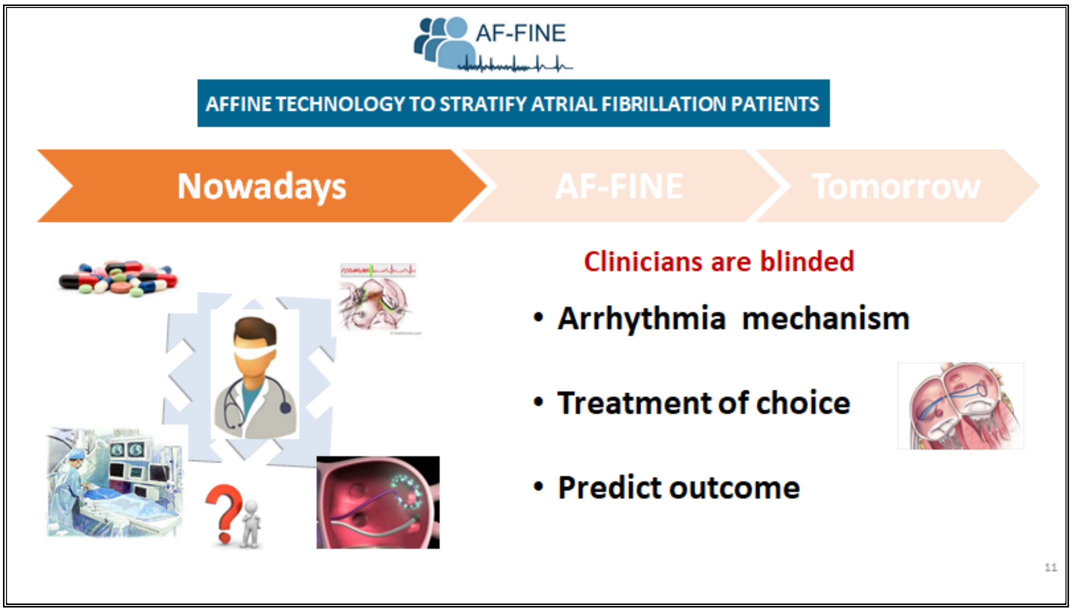
Stratification – AFFine project

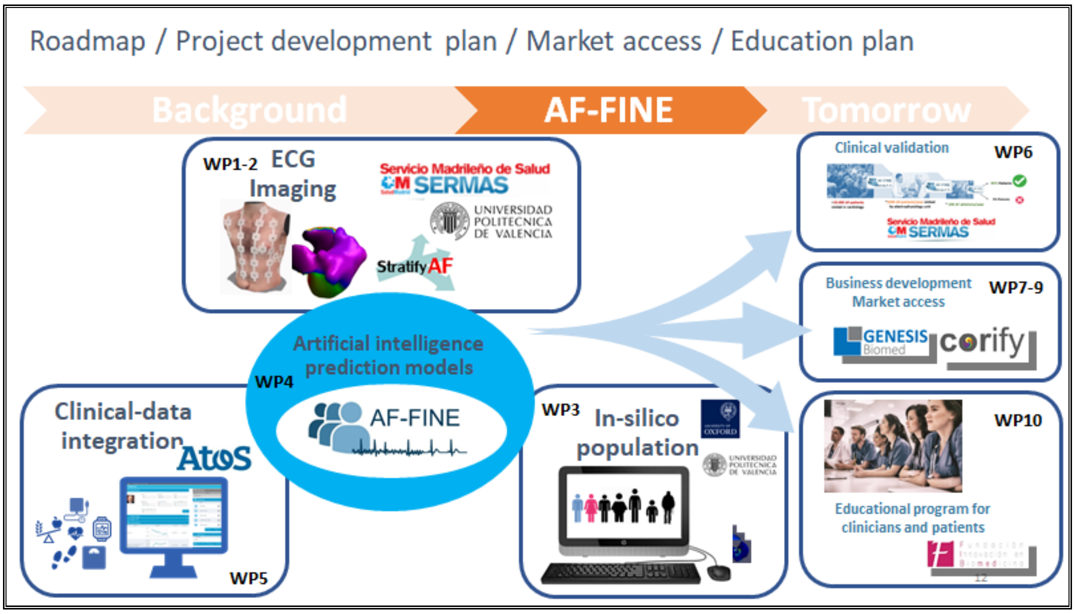
Atrial Fibrillation (AF) mechanisms can be difficult to predict. It is not always clear where the data is coming from, what the treatment of choice should be (drugs, ablation) and, therefore, what the clinical outcomes might be.

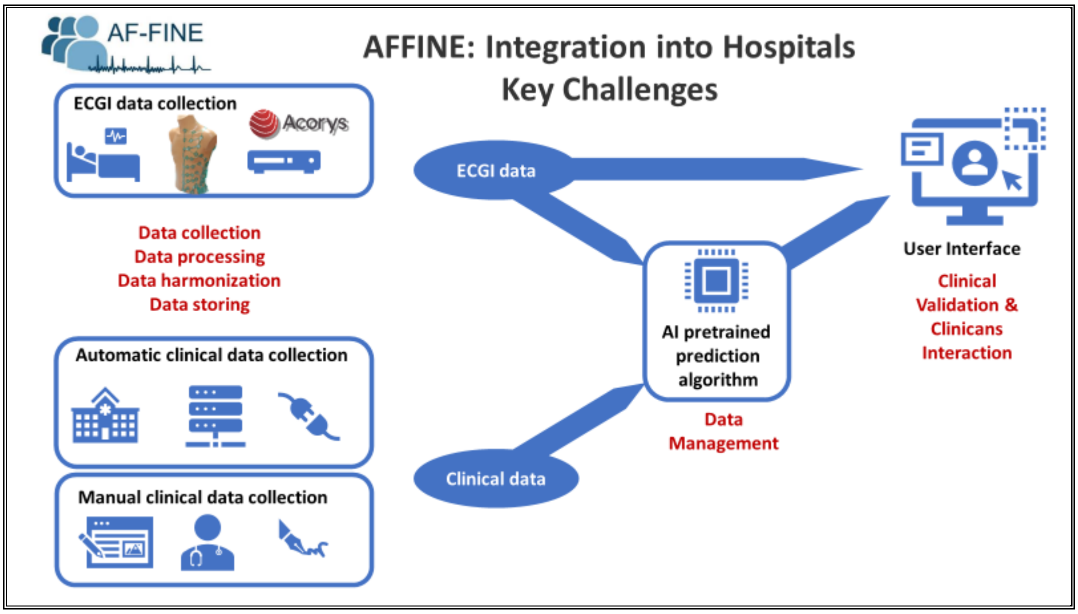
The AF Fine project, funded by EIT Health, aims to find ways of stratifying AF patients by conducting a range of studies (non-invasive body surface readings and invasive - angiograms) and undertaking In Silico analysis to develop models that learn from the AF process.

The different areas of knowledge have been integrated into an AI predictive model to determine clinical outcomes for different types of AF patients. The team has developed a business management programme to integrate the AI platform into the current system; and are applying learning from the process to share with the electrophysiology healthcare community and cardiovascular students.

A number of challenges have been identified relating to data: for example, the collection process, harmonisation, storage, introduction into existing data management systems; and validation /usability in healthcare systems.


AF-FINE
AFFINE TECHNOLOGY TO STRATIFY ATRIAL FIBRILLATION PATIENTS
Nowadays
AF-FINE
Tomorrow
Clinicians are blinded
• Arrhythmia mechanism
• Treatment of choice
• Predict outcome
11


Roadmap / Project development plan / Market access / Education plan
Background
AF-FINE
Tomorrow
WP1-2 ECG Imaging
Servicio Madrileño de Salud SERMAS
UNIVERSIDAD POLITECNICA DE VALENCIA
StratifyAF
Artificial intelligence prediction models
WP4
AF-FINE
Clinical-data integration
AtoS
WP5
WP3 In-silico population
Clinical validation
WP6
Business development
Market access
WP7-9
GENESIS Biomed
corify
WP10
Educational program for clinicians and patients


AF-FINE
AFFINE: Integration into Hospitals
Key Challenges
ECGI data collection
Acorys
Data collection
Data processing
Data harmonization
Data storing
Automatic clinical data collection
Manual clinical data collection
ECGI data
Clinical data
AI pretrained prediction algorithm
Data Management
User Interface
Clinical Validation & Clinicans Interaction

Theme 1: Patient data, data partnerships and shared access

If data is the foundation for AI, then it is not surprising that this discussion focused predominantly on the need to strengthen data quality, governance, security and inter-operability – considerations already set out by EIT Health and McKinsey and Company[ix]. In addition, the **European League Against Rheumatism (EULAR)** suggest that their Points to Consider (PTC) for the use of big data within the field of rheumatic and musculoskeletal disorders (RMDs) could be applied by other medical disciplines.[x]

Data is becoming more and more important across all aspects of the health spectrum. Medical imaging data for example contains a wealth of information that can be used to enable modern healthcare approaches like precision medicine and population health:

> *"Medical imaging, especially X-ray based examinations and ultrasonography, is crucial in a variety of medical setting and at all major levels of health care. In public health and preventive medicine as well as in both curative and palliative care, effective decisions depend on correct diagnoses. Though medical/clinical judgment may be sufficient prior to treatment of many conditions, the use of diagnostic imaging services is paramount in confirming, correctly assessing and documenting courses of many diseases as well as in assessing responses to treatment."* [xi]

In 2016, the Beth Israel Deaconess Medical Center (BIDMC), Boston, USA, [xii]was able to demonstrate high accuracy X-ray readings using an AI algorithm[xiii] which signalled a fast-growing interest in the application of AI in healthcare.

Over the last few years, companies such as Google have started to focus on imaging interpretation and analysis, in turn creating partnerships that allow them access to patients' data. A number of strong collaborations between healthcare providers, academic partners and big companies have followed. Protected access to specific data may allow these companies to explore new avenues for clinical data use; and help to cement their place in the new data revolution. While big data outside of healthcare is large and complex, it can provide some great opportunities for smaller companies. EIT Health technical partners have reported positive conversations with corporate giants: suggesting that smaller companies could be well placed to explore the potential benefits of collaboration such as increased understanding of the competitive landscape, and exit strategy opportunities.

The storing of data for prolonged periods may or may not be a choice. We know that hospitals, primary and secondary care organisations, and academic institutions still face challenges relating to privacy, regulations, and technical limitations. Generally speaking, inter-operability and data transfer systems are not sufficiently developed, and continue to present problems around data sharing. EHRs / EMRs and clinical trials hold significant amounts of data which could go a long way to improving the quality of care if they were made more widely available. There is however some progress being made around inter-operability. Take **IMAGEENS**[xiv] for example, a French-based company created to build market-ready medical image processing software based on DeepTech technologies. Their deployment of cardiovascular imaging technology with other AI components for labelling and data quality improvement can create the inter-operability necessary to build training datasets for AI algorithms. Furthermore, their partnerships with x40 data warehouses have led to further possibilities for the development of new diagnostic tools.

In theory, data from published studies should be available through Open Access[xv] but it can be difficult to obtain despite useful and helpful guidance such as the 'FAIR guiding principles for scientific data management and stewardship'.[xvi] EULAR's task force referenced this issue in their 'Points to Consider for the use of big data' and identified a need for pilot projects to assess the impact of data sharing, and for this data sharing to be evidence-based[xvii] - a point which warrants further debate.

Theme 2: Data quality and trust

Healthcare professionals have put a lot of trust in data over the decades, taking important decisions from the findings. The Nurses' Health Study, now in its third generation, has seen more than 280,000 participants contribute to key scientific knowledge through the study of diet, lifestyle and genetics[xviii]. These contributions helped identify important public health issues such as the links between smoking and cardiovascular disease (the world's highest cause of death[xix]), and between postmenopausal obesity and breast cancer. The message here is that accurate patient data produces accurate and trustworthy results: 'quality in, quality out' including varied and large-scale studies.

As AI in healthcare evolves and becomes even more sophisticated, there is a continuous need to ensure that the data is trustworthy, allowing physicians to make the right clinical decisions and protect their patients' interests. The first rule in generating trustworthy data is to ensure that only high-quality and accurate data is entered into algorithms, thereby avoiding a 'quality in, quality out' scenario *i.e.,* where resulting data analytics, applications or (business) processes are rendered unreliable[xx]. Fundamentally, the data typology itself needs to be appropriate. In the case of AI in cardiology for example, analogue ECG graphs need converting into electronic data sets before being introduced to the algorithm.

The amount of data available can affect efforts and methods to identify what is quality data. It was reported by data analyst colleagues that up to 70% of their time can be spent 'cleaning' data. These heterogenic inaccuracies can create challenges in identifying real-world data among large repositories. Some roundtable participants suggested a strong focus over the next few years on systems for automatic quality checks.

Clinicians, technicians and entrepreneurs continue to push innovation by finding ways to improve healthcare, while making it more accessible and more affordable. Every stage of development, testing, implementation and evaluation necessitates further generation of evidence to prove that the new intervention/device/system is superior to what already exists. Trust and quality in data, algorithms, and AI elements overall are paramount in securing the relevant certification and approval and, ultimately, access to market.

In addition to primary data, algorithms are often fed data from publications. This can be a very lengthy process requiring multi-disciplinary work to agree what constitutes quality data, and how to manage conversions between different sets of data (e.g.: between different formats, platforms or different pain scales). Roundtable participants brought forward examples of only being able to use 1% of data based on an initial selection of 350,000 articles. In another study, patient data was interrogated directly, and only 33% of the data was deemed useable for one health topic.

Assuming that the data introduced into the algorithm has quality, then the outputs should also be of a quality standard.

The 'black box' of data layers remains an issue though: while algorithms can provide reliable probabilities, it is not always clear for the physician how that probability was calculated within the 'hidden layers' in the neural network. This could be addressed to some extent by using alternative/additional data such as physiological measurements from biomarkers, or other evolving techniques to build on AI explainability. In addition, there are technical solutions to this issue such as machine-learning systems that rely on image analysis. These can generate saliency maps that show which area of the image was the most significant factor contributing to a diagnosis or prediction[xxi].

It may be difficult to translate an AI solution to another health condition, or physically transport it to another healthcare provider, but these efforts could present good opportunities for prospective data validation. A system that is already trained, for example, could potentially be used for the same condition in another healthcare setting; and/or adapted for use in a similar programme at a different hospital or clinic creating market opportunities for the manufacturers and developers. This brings to light issues around evidence, error and bias:

> *"…algorithms typically perform well with data similar to the data they were trained on, but their performance can be significantly worse if the data are different, reflecting a different population's characteristics. To address this, AI providers need to proactively train and validate models on different, large independent datasets"*[xxii].

Theme 3: Workforce education, multi-disciplinary teams and collaboration

> ***"Artificial intelligence (AI) has the potential to transform how healthcare is delivered. Yet we need to understand the impact of AI on the healthcare landscape to pave the way for the adoption of AI solutions at scale. That's why EIT Health is exploring …… the impact of AI on healthcare organisations and the workforce".***
>
> - *EIT Health and McKinsey*[xxiii]

This report has touched on the importance of training towards machine learning and the role of physicians in educating and empowering their patients through the clinical application of AI. AI and algorithms are powerful tools but - even when fed with quality data – can yield results that are open to misinterpretation, or different interpretations. Naturally this affects information management and analysis, crucial clinical decision making, and final outcomes. Understanding and addressing educational need among the workforce is paramount to the success of AI in healthcare and must include multi-disciplinary working at its core[xxiv]. Educational initiatives such as **HelloAI**[xxv] and **HelloAIRIS**[xxvi] help medical students and professionals gain the skills they need to adapt to the changes in healthcare that are caused by an increasing reliance on AI.

Education in health innovation needs to take into account the wider ecosystem, in particular relationships between healthcare professionals and start-up companies. This is one of the reasons that Start-ups meet Doctors was developed. The EIT Health and McKinsey report found that only 13.9% of Start-ups felt that collaboration with healthcare professionals during the design phase was important. Collaboration to identify unmet need was slightly better at 21.3% but 75% of Start-ups felt that testing did <u>not</u> need to include technical healthcare professionals.[xxvii]

Some of the most successful Start-up companies involve healthcare professionals as key stakeholders throughout the entire design phase. Take Unhindr for example – a UK based Start-up who developed a prosthetic device which can be adjusted for maximum comfort, and whose AI component automatically adjusts to the amputee's preferences following a period of machine learning[xxviii]. While many innovation ideas are borne from individual experience of, or exposure to a certain condition, other entrepreneurs will identify solutions for conditions that they are not personally familiar with. In these cases, success depends very much on the level of interaction with the right stakeholders, including users: from finding a common ground, collaborating in all design phases, testing, further development, and scale up. For these kinds of solutions to make it to market, a certain amount of data and ideas have to be shared. Information can be 'filtered' to gain the interest of larger corporates for acquisition, and/or to identify opportunities to collaborate with smaller companies, without 'hoarding' everything and exposing pending patents.

Some participants suggested that conversations between physicians and designers could start from a different perspective. As an example, clinicians could benefit from an appreciation of the technology's qualities and what it <u>could</u> be used for. This is a different approach to asking 'why' it was developed. Developers, students and designers may reach a better understanding of the scope of use for their idea; with the added advantage of early validation from a clinician/KOL. These kinds of conversations could be considered as educational methods around product design and development.

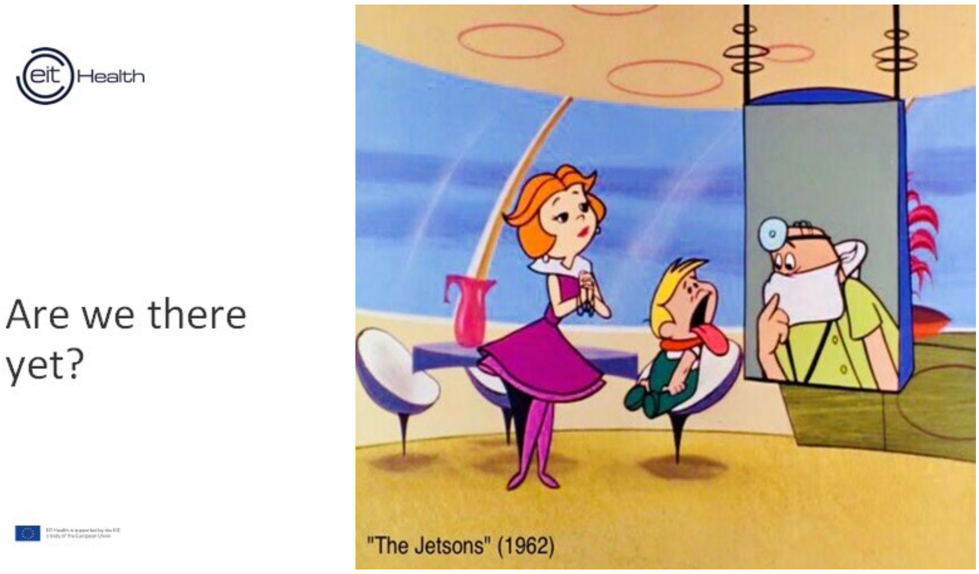
Some clinicians have established their own successful Start-up companies, which has enabled them to further pursue clinical innovation, practice, and trials with AI solutions. Existing strong relationships with hospitals provided readily available test-beds, speeding up validation and the route to market. As a result, several other companies are interested in collaborating. In the interests of selecting the right partners and projects, it is recommended to define a pipeline process: consider why a particular company would be good to work with; and what will be improved as a result. Adopting such methods and processes should help drive clinical innovation; and ensure that projects, collaborations and interventions have impact and deliver high value care for patients.

Conclusions and recommendations for further clinical innovation and collaboration in artificial intelligence

The body of evidence collected during this roundtable demonstrated a number of areas which need to be addressed in order for artificial intelligence in health innovation to be successful in the long term. Conclusions and recommendations include:

- There is a growing need for data integration and a common language between different disciplines.
- Smaller companies should seek to understand why some larger companies 'store' specific datasets. This may help to create a clearer picture of the competition and inform the next stage of their journey.
- More can be done to make published data more easily available through Open Access. Individuals and organisations should encourage each other to follow the 'FAIR guiding principles for scientific data management and stewardship'[xxix] in the interest of building more effective working relationships in and across health ecosystems. There is a need for pilot projects to assess the impact of data sharing, and for this data sharing to be evidence-based.[xxx]
- Systems capable of running automatic quality checks on data will free up time for analytical teams, and are a clear area for development.
- More solutions are emerging to help us understand 'black box' data layers: by using alternative/additional data such as physiological measurements from biomarkers, other evolving techniques to build on AI explainability, and more technical ways such as machine learning to generate saliency maps.
- A need for data science medical education was identified.
- Start-ups, entrepreneurs, and clinical innovators need to engage all relevant stakeholders at all relevant stages including design, testing, development, implementation and scale up. Ideas can be protected by 'filtering' the type of information which they share.

- Start-ups and Doctors should consider a different kind of initial conversation to collectively understand the wider scope and best application(s) for an innovative solution – based on its qualities rather than the reason for its design.
- Organisations should consider a 'pipeline process' to help them decide the best time to get involved with a particular startup, based on the desired results from collaborating. Such approaches could help demonstrate impact towards high value care.



APPENDIX 1

An introduction to Artificial Intelligence – Prof Felipe Atienza

In the most part, conventional statistical methods are based on the inference principle (the generation of new logic based on old logic and/or evidence) but data distributions should meet stringent assumptions such as numbers, distribution and typology and this is not always the case. AI is used to manage complex, heterogenous and multiple, rich, multimodal data sets with multimodal data coming from different areas, for example ECG, imaging systems, etc.

Machine learning techniques are iterative programmes that manage the data, identify patterns and make decisions but the most developed AI method is deep learning, based on an artificial Neural Network that uses specific mathematical expressions for the learning learn process and to extract high level features from the raw data[xxxi].

Neural networks can be fed with different types of data, for example medical records, pure electrical signals and medical images, where medical images present the most complex kind of data. This combined data is then introduced into an ‘input layer’ before being fed into different ‘hidden layers’ to reach a specific medical outcome, for example sinus rhythm or Atrial Fibrillation[xxxii]. These networks, however, need to be trained - through supervised and/or unsupervised learning. **Supervised learning** methods (e.g., deep learning) feed labelled data into the system; that is, the patient outcome is already known. In the case of cardiovascular medicine for example, this might be Atrial Fibrillation (AF) or non-AF / sinus rhythm. The machine learns from the relationship between inputs and outputs, and this feedback can be used for further training. Another method to train the neural network involves introducing unlabelled data through **unsupervised learning** (e.g., cluster analysis), where the patient outcome is not known. In this method, the system itself creates clusters which aggregate the different types of inputs (in the case of cardiovascular medicine - ECGs), allowing the machine to suggest different patient outcomes i.e., hypertrophic cardiomyopathy (HCM), sinus rhythm, or AF[xxxiii]. The use of unsupervised learning therefore allows physicians and researchers to learn from the machine as well as training the machine.

APPENDIX 2

Participants

Medical Doctors and Clinicians

- Felipe Atienza, Clinical Chief at Gregorio Marañón General University Hospital, Madrid, Spain
- Luís Martí Bonmatí, Director of Medical Imaging at La Fe University and Polytechnic Hospital, Valencia, Spain
- Balazs Gasz, Associate Professor at University of Pécs, Hungary
- Laure Gossec, Professor of Rheumatology at Pitie-Salpétriere Hospital and Sorbonne Université Hospital, Paris, France.

Start-ups and Entrepreneurs

- Robert Baldwin, CEO at IMAGEENS
- Helene Schönewolf, CEO at RAMPmedical
- Ugur Tanriverdi, Bioengineering Scientist and CEO at Unhindr
- Clemens Tepel, CEO and Co-Founder at DeepSpin

EIT Health Staff and Collaborators

- Cristina Bescós, Managing Director at EIT Health Spain
- Irene Sánchez, Business Creation Manager at EIT Health Spain
- Joan Guanyabens, Medical Officer at EIT Health Spain
- Daniela Dias-Santos, Startups Meet Doctors moderator
- Kirstie Crowther, Startups Meet Doctors rapporteur
- Mara Belluco, Events and Engagement Officer at EIT Health Spain

APPENDIX 3

Reference material and further reading

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[xxiii] EIT-Health-and-McKinsey_Transforming-Healthcare-with-AI.pdf

[xxiv] EIT-Health-and-McKinsey_Transforming-Healthcare-with-AI.pdf

[xxv] HelloAI: Summer school about artificial intelligence in healthcare

[xxvi] HelloAIRIS - EIT Health

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