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How To Jump Aboard The New EU Innovative Health Initiative Train And Where It Is Heading

by Amanda Maxwell

For MedTech Europe's Patrick Boisseau, the newly launched Innovative Health Initiative is a real "game changer." In this interview, he explains how companies should get involved in cross-sectoral medtech/pharma projects that will revolutionize European healthcare innovation.

Patrick Boisseau, director general industry strategic initiatives at industry association, MedTech Europe, spends 80% of his time working as the representative of MedTech Europe on the governing board of the EU's Innovative Health Initiative, part of the Horizon Europe program. He believes the project will have a "major impact" on future healthcare delivery through the convergence of innovation in medtech and pharma on a scale never seen before.

Through cross-sectoral initiatives, the IHI aims to create "really new ideas, new contexts, new products and new solutions for patients" through pre-competitive research, the results of which will benefit us all as patients, Boisseau told Medtech Insight during a recent interview. His passion for the topic really brought the scheme, and its exciting potential, to life.

"You can easily imagine that healthcare delivery in 5-10 years from now will be very different from today and that medtech and pharma companies will be very different too," Boisseau predicted. Not that the aim is to merge the industries, but rather to maximize their cross-sectoral potential, he emphasized.

The MedTech Europe Director added that digitalization is probably the most powerful tool to create convergence in innovation between the different sectors, with applications in robotics and artificial intelligence among other cross-cutting topics that will help revolutionize the way the

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IHI projects can flourish.

Boisseau explained during the interview how the medtech industry can become involved and benefit and when, how funding operates, and spoke of the initial projects and of the uncertainty around UK industry involvement, amongst several other observations relevant to this new healthcare revolution.

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PATRICK BOISSEAU

Q Medtech Insight: Why is IHI so important to the medtech sector?

A Patrick Boisseau: This is the first time that the medtech industry is being considered as critical for the deployment of healthcare delivery in the context of EU research and funding programming. We now hope to be able to deliver truly integrated solutions by joining forces with the pharma industry.

This IHI initiative reflects the reality of what happens in care: by developing these treatments together then they can be integrated more easily into the workflow at hospital level.

- What do you see as the most positive elements of increased cooperation between the pharma and medtech industries?
 - PB: Five industry associations from across the medtech and pharma sectors MedTech Europe, COCIR, EFPIA, EuropaBio and Vaccines Europe have been working together with the Commission for two years to shape IHI. Witnessing IHI create not only the framework, but the mindset and spirit for cooperation between the pharma and medtech sectors, and seeing this reflected even within individual companies, is one of the highlights so far.

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The medtech and pharma industries have been discussing new topics in an increasingly open way. IHI is a place where medtech and pharma solutions will be proposed and designed together. This is really new.

- We are seeing increasing overlaps between medtech and pharma, especially at the technology level. What does this mean for regulation?
 - A PB: The regulation of medical devices, IVDs and pharma will remain different. IHI's objective is not to work towards a single model of regulation. It is not about merging the two industries. It is much better that each industry keeps its specificities, models and references, but that by joining forces we can develop concepts that were not able to be designed by one single industry sector.
- Who do you expect to respond to calls for interested individuals for the new IHI governance body, Science and Innovation Panel (SIP) which is expected to be launched in March?
 - MedTech Europe will all have a presence on the panel. IHI has launched a call for expression of interest recently to attract new, external participants representing the various stakeholder groups in healthcare. We want all people that have a say in healthcare delivery around the SIP table, healthcare professionals, regulators, patients, opinion leaders and academics SIP's role will be to fix the IHI's future priorities and propose to the governing board the future topics for funding.
- Q In terms of the budget, would you like to explain how that is being divided?
 - A PB: The total budget for IHI will amount to €2.4bn (\$2.7bn) over 10 years. Because it is a public/private partnership, half of the budget for each project will come in cash from the European Commission and half in kind, mostly from industry and also some from contributing partners.

Contributing partners are organizations that are not members of the healthcare industry – like charities, foundations or companies from a totally different sector –

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such as the chemical, digital or IT industries. They can also participate in projects and make their own contribution.

- Q Can you explain what "in kind" contributions will include?
 - A PB: In kind encompasses people, equipment, consumables, access to databases/prototypes, clinical trials etc. There are many ways that companies may mobilize their own resources.

Once the European Commission has assessed the value of industry's contribution, it will match the amount.

- You spoke about €2.4 bn being spread over 10 years. Is there likely to be a greater input at the beginning or will it be evenly spread across the 10 years?
 - A PB: We were supposed to start the projects in 2021. As they will now start this year, the budget will be spread across nine years now.

Because the concept of IHI is new for many potential contributors, we have foreseen a ramping-up phase during the first three years to give everyone a chance to manage the initial learning phase.

The intention was to allocate €200m this year, and E300m next year, and then some E350m a year over the next years. The budget is fixed annually by the governing board. We aim to align the budget required for implementing the calls selected by the governing board.

I understand that areas likely to be the subject of the first call for research topics are: precision oncology, innovative patient-facing care pathways for patients with neurodegenerative diseases and comorbidities, access and integration of heterogeneous health data for improved healthcare in disease areas of high unmet need, and next-generation imaging and image-guided diagnosis and therapy for cancer. How will MedTech Europe respond to this

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and help its members and how will it involve other medtech industry associations?

A PB: The summaries of the draft topics are shortlisted on the IHI website following discussions between experts from the European Commission and the industry associations.

One key eligibility criteria for IHI participation is that there is cross-sectoral contribution. If you look at these six topics, you will see that none is specific to one sector only. COCIR, the EU trade association representing medical imaging, radiotherapy, health ICT and electromedical industries, for example, proposes medical imaging in oncology to be one topic – but if it were just a medical imaging project, it would not be eligible for IHI; so we will have IVD and digital companies participating too.

A significant number of companies in the medtech sector have expressed an interest in one or several of these six topics; and in some cases, medtech companies are promoting an idea where they could take the lead, and in others they plan to contribute to a project led by another company, maybe a pharma company.

There are many different scenarios. But all in all, the medtech sector is responding very positively to this IHI initiative, even though it has almost no previous experience of projects in European public/private partnerships. Medtech companies are learning very fast and becoming effectively involved.

Q Can you explain how the industry will get itself into position to benefit from the projects and the funding and when? How will the process of getting consortia together work?



A PB: The first calls are expected to be published in late June this year. The summaries are already available. Although we are still at the early discussion stage, the public stakeholders and private companies are starting to mobilize their personal networks and think about how they could combine their different expertise and later form a

consortium that will write a proposal to address one of these topics.

- Q Is there any help for those who wish to become involved with networking?
 - A This is not an easy exercise, especially for newcomers in these European research and innovation community. So, to help potential public and private participants into projects, the IHI office will organize a public brokerage event, probably in June or July. The precise date is not fixed yet. We hope it will be face-to-face because networking and brainstorming together is very challenging if you do it remotely.

Any potential partner, public or private, can attend, listen to the presentations on the six topics and then start discussing opportunities with those present, including talking about forming or enlarging existing consortium.

There will also be a partner search tool available on the IHI website for those looking, for example, for specific expertise to add to their consortium. IHI will organize this public brokerage event every year and we would expect to have a growing community of public and private partners that exchange ideas.

- It sounds as if the IHI website is going to play a really key role in terms of allowing access to information and enabling people to find they information they need to start getting involved?
 - A PB: That is right. The www.ihi.europa.eu website is a source of information on all aspects of IHI, not just future topics, but also the rules of participation and events. I would recommend that interested parties look at it before thinking about being involved. This is the only place where you can connect to all the official information about IHI.
- Q Can you explain the process about the selection of topics and how and when interested parties can keep abreast of developments and become involved?
 - A PB: As soon as it is in operation, probably in later March, SIP's first task will be to evaluate these six draft topics, looking at if they are aligned with IHI's objectives.

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Once the SIP has delivered its recommendation to the governing board then the governing board will take the final decision and grant the final approval for the topics to be officially published, which is expected in late June. At that point, the topics will be published on the IHI website and anybody can apply.

After that there will be a period of some three months for the consortia to write their proposals and submit them. The deadline for submitting the full proposals is expected to be sometime around end of September.

After all the bids have been submitted, there will be an external and independent evaluation of all the bids which will be supervised by the IHI office. It will evaluate the bids and its ranking will be submitted to the governing board. This is expected before the end of 2022.

Q This is quite a long-winded process. Do you hope it will become faster?

A PB: The European Commission and industry associations are trying to shorten the intermediate steps. It will take longer this year because we have to set up the SIP first. In coming years, the SIP will be established, and it will be faster to move from idea to project. Every year, the governing board will review the timing and try to shorten it whenever possible.

Q Also, do you see SMEs getting as involved as larger companies?

A PB: Legally speaking all companies can participate and they are encouraged to as well: start-ups, SMEs, mid-sized and big companies.

We expect a stronger participation of medtech SMEs in IHI than in pharma because they are the key innovators in our sector.

The medtech sector has a lower in-house research and innovation capacity compared with pharma. It relies more on innovative start-ups and SMEs that are developing

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concepts and then, at a later stage, the medtech companies deal with these start-ups to help with the final steps of clinical and regulatory validation and market access.

Q How easy will it be for start-ups and SMEs to become involved?

A Start-ups are so busy that they do not have the time to attend or participate at European association level. So MedTech Europe is frequently informing its national associations to make sure their members are aware of the opportunities and are trained and ready to spread the word and opportunities at national level.

We have already had some positive feedback from the start-ups that have been expressing interest in joining the consortia. We should, therefore, have an increased in the participations of SMEs and start-ups over the coming years in IHI.

In terms of the strength of participation of medtech in IHI, do you think IHI could be even more relevant to the medtech industry than it has been to the pharma industry?

A PB: The pharma predecessor to IHI, IMI, has been very successful. There have been 200 projects over the 14 years of operation. And there have been key successes, such as the Ebola vaccine. There needs be no discussion about the success of IMI.

The later years of IMI were like a pilot for IHI with some of our members companies – IVD and medical device companies alike - participating on a limited scale to some IMI2 projects.

But IMI members realized at the time that if they continued to fund pharma-only projects, then they would miss some objectives and answer only partly the objectives and needs of the healthcare systems which is why, over the years, IMI2 evolved and opened the door to other industries.

Within IHI, the objective is to have an equal contribution from the pharma and the medtech sectors – in terms of budget, and in terms of company participation. So,

medtech and pharma are jointly driving IHI initiatives on an equal footing.

Q When will future topics be decided upon and how?

PB: The second campaign, or the second wave of IHI calls, is expected around the end of the year. It may be in December; the date is not fixed yet.

The brokerage event in early summer that I mentioned will be a good opportunity to share future ideas. The generation of ideas will be helped because the significant difference between IMI2 and IHI is the degree of openness and transparency in the prioritization process.

In practice, external stakeholders, be it a patient association, a scientific society, or indeed any organization that is not a company, has four ways to bring ideas to IHI.

- The website, where there will be a template for suggesting ideas for future programs. These ideas will be screened and analysed by the SIP
- Stakeholders can present ideas to the SIP. If the European Society of Cardiology is a SIP member, for example, you could contact it saying you have a bright idea in cardiology and ask them to share it with the SIP.
- Through EU member states, because all the member states and associated countries under the Commission will sit on State Representative Group. So any country could say we should invest more in oncology, or increase efforts on pediatric diseases, for example.
- Attending the brokerage event. There you can interact live with companies, with the SIP and with the European Commission.

Q Overall, who do you think will benefit most from IHI?

PB: I can see many different target groups that would benefit. But, for me, there are three main target groups: one is the healthcare professionals as we expect to deliver integrated solutions that would more easily fit into the current work stream at the hospital or at home. The second category are the patients and citizens; and then there is industry too, in the wide sense, because small companies and start-ups will benefit if Europe is made more attractive again for healthcare research and innovation.

We know from, let's say, some overseas companies that have activities in Europe, that IHI could be a game changer for them. If an overseas company realizes that because of IHI the innovation ecosystem in Europe is more attractive, they will move their investments towards Europe. This would benefit companies, the workforce,

Q So can companies outside Europe become involved?

PB: Yes, but there are some limitations. We are aiming to implement this research and innovation ecosystem in healthcare in Europe and IHI is funded significantly by the European Commission and public money.

However, we still want to access scientific excellence available overseas.

members states and be beneficial for the healthcare value chain.

That is why companies with some non-European divisions, can participate: but their participation will be limited to 20% of the budget of a project. They can participate more, but their participation will not be matched by the European Commission above this limit.

Most pharma and medtech are global, and they have some of their excellence centres based outside Europe. So a US-based division of a European company can still contribute to the project, but their contribution will be limited to 20% of the project's value, for example.

Q What about involvement of organizations from Switzerland or the UK?

A PB: For now, Switzerland will be considered like the US, as a non-EU partner.

We do not know at the moment whether they UK partners can participate as European contributors or associated to Europe. We are awaiting clarification from the European Commission. No one knows how long this will take.

We really hope to have clarification before publication of the first calls. Otherwise, it

will create uncertainty and UK-based entities may hardly participate in IHI, or only to a limited level. It will be a shame if European citizens cannot benefit from this UK expertise, as the UK has strong assets in R&D in the pharma sector, especially, but in the medtech area too.

- Medtech Insight has recently published an article on the launch of a call for individuals interested in sitting on the SIP which explains the history of IHI and gives an overview from executive director, Pierre Meulien. (Also see "<u>Devices, Diagnostics, Digital & Drugs: Europe's New R&D Venture Presents Its Agenda</u>" Medtech Insight, 31 Jan, 2022.)
- For an earlier introduction to the topic of IHI, see an article in In Vivo, Medtech Insight's sister publication, (Also see "Medtech's Place In Health Care R&I Boosted Under Horizon Europe" In Vivo, 27 Jul, 2021.)