Healthcare

1. What are the biggest needs and gap such TEFs could fill in your Member State or in Europe?

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(1/4)

- Testing and validation of pilots, in labs or hospitals, regulatory sandboxes
- To provide a testing place with various facilities for AI products/services to finally have them adopted. What I see is missing is the "correct" regulatory path and connection to MDR, but also the reimbursement issues. The TEFs must be connected with the European Health Data Spaces.
- Access to quality data.
- validation and certification services not only for startups but also for established companies
- Collaboration between stakeholders in the EU member states.
- a. Access to research infrastructures for real environments testing (i.e., a researcher going to a TEF facility to another country and possibility

1. What are the biggest needs and gap such TEFs could fill in your Member State or in Europe?

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for SMEs to test their products and services in real life). b. Sharing best practices in Robotics, AI, Active Assisted Living testing. c. Help sustaining the scalability and adoption of AI/Robotics solutions in Europe. d. Contribute to standardization and legal framework for AI/Robotics based solutions. e. Making full power of the computing power in Europe as well as of multidisciplinary deriving from AI and robotics

- Access to read word data and end users (citizen and healthcare practitioners) to test the AI based medical technologies, Centre of expertise which can advise SMEs on applicable legal and regulatory frameworks and support on compliance
- *
- To allow observation of clinicians' behaviours when interacting with medical AI To allow testing of AI systems with clinicians with minimal regulatory

1. What are the biggest needs and gap such TEFs could fill in your Member State or in Europe?

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restrictions To improve the speed with which AI systems can be tested, revised, and re-tested in health care. To test medical AI systems in ex-vivo conditions close to real life - for example using medical simulation. To help develop AI systems that seek to improve clinicians' learning and performances with actual patients instead of only focusing on how to automate and replace clinicians.

- understand AI challenges (e.g. ethical and societal challenges in real life) and uncover "solutions" to move forward, embedding care in dalily life and enhancing prevention and wellbeing
- o Access to research infrastructures for real environments testing (i.e., a researcher going to a TEF facility to another country and possibility for SMEs to test their products and services in real life). o Sharing best practices in Robotics, AI, Active Assisted Living testing.

1. What are the biggest needs and gap such TEFs could fill in your Member State or in Europe?

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(4/4)

o Help sustaining the scalability and adoption of AI/Robotics solutions in Europe. o Contribute to standardization and legal framework for AI/Robotics based solutions. o Making full power of the computing power in Europe as well as of multidisciplinarity deriving from AI and robotics

2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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- Could be both, and also e.g. SME incubators, preferrably all three in combination?
- Please consider also the regulatory framework for MD (MDR745/2017): TEF should have a easy access to approval/pre-approval
- rehabilitation institute
- Home environments which would represent the diversity of the different architectural settings
- HOspitals should not be the only centers for a TEF. We should also envisage social care departments of municipalities or regions
- A research Institute of Applied Innovation with access to multiple hospitals, home environments and public authorities as well as companies. Such organizations have the capacity, know how and connections to do the

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work. Hospitals as a norm are providing healthcare, so it is not easy to have doctors and healthcare professionals taking time from their work in regular basis to test and validate.

- A network of EU-distributed facilities to cater for cultural and language differences, especially if you target patients/citizen

involvement. Also health care systems are irganised differently and often on local/regional level in the different MS.

- Not online hospital. Primar cate and público health facilities too
- Older adult environmental friendly areas (villages; cities; neighbourrhoods)
- A university hospital should include a technical university for testing in clinical frame,

2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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(3/7)

a village is close to real life e.g. for chronicity management, prevention, ...

- public health care system
- Network of univ hospitals focusing on AI and decision support for physicians to engage with tech developers and work on data
- consortium between university hospital, enterprise incubators, software companies
- A facility with access to hospitals/homecare services (patient and healthcare practitioners), AI tests knowledge and tools, access to healthcare data (read, anonymized), strongly connection with innovation ecosystems.
- TEFs should be affiliated with healthcare organisations where health data is produced, where the data is standardised and comes with consistent formats and nomenclatures.

2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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An added benefit: the TEF could support the optimal integration of AI systems in the affiliated hospitals, including organisational arrangements, workflows and capacity-building.

- Hospitals, labs
- An ecosystem of: 1 coordinator - SMEs - RTO - Industry - Facility
- TEF facilty in a Healthcare Sector need to have a Hospital at the center. where the real needs are met. TEF should not be base in an academic environment, or RTO. The Hospital need to meet some specific requirements to be able to offer the service of testing and experimentation facilty. IT infrastructure +

2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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Culture of patient engagemnt + Regulatory and clinical validation expertise so that the validations are made in the correct regulatory way to meet the market. Also, there should be a network of federated data so that it is possible to validate solutions in different environments. The case for paediatrics should be well represented. This is a proactive approach to a healthier society. From fetal period, mother wellbeing, until the end of the developmental period. This has an important effect if the whole individual life. Pediatric data, characteristics are different from adults. Both aspects whould be taken into account in a TEF Healh Facility.

- A
- An ecosystem involving several tools from data, access to real clinical settings (hospital, home, work), and other support services

2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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- A university hospital with access to testing facilities such as large-scale medical simulation using physical simulators, such as virtual-reality simulators or mock OR rooms.
- a village testing active and assisted living technologies
- a. A Health TEF could be an ecosystem represented by a hospital, a network of (national and international) SMEs; a research centre/infrastructure (with labs and real environment testing possibilities); standardization/regulatory bodies; a supranational coordination actor. b. Sectorial Health TEFs should be able to interact and collaborate to boost the innovation potential created by the facilities.
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2. What kind of TEFs would you have in mind? For example: a university hospital with access to patients, a village testing active and assisted living technologies?

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- In areas like pediatrics, A tef should be centered in an academic children's hospital in consortium with other academic centers with pediatric care and support by other stakeholders

3. Which are the existing facilities in your Member State, which could be upgraded to a TEF?

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- The CR: Universitiy Hosptita Olomouc
- Friuli Venezia Giulia Eco System
- Large hospital trusts and assistive care centres with University and medtech innovation support
- In Western Hungary we are capable and motivated to host health test functionality with hospital and care organization
- in Italy University hospital experimenting AI technologies as clinical research
- In Italy I mean, the cyberhospital so southern europe
- Germany: University hospitals
- Nordic Network of testbeds representing several test bed facilities from Nordics
- Rehabilitation centres with R&D knowledge
- In Denmark: Copenhagen Academy for Medical Education and Simulation (CAMES) Copenhagen University Hospital Rigshospitalet Danish Technical University (DTU)
- We have a very good network of Test beds in

3. Which are the existing facilities in your Member State, which could be upgraded to a TEF?

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conjuction with hospitals in Finland, including all necessary stakeholders.

- Eindhoven MedTech Innovation
- Multiple University Medical Centres in the Netherlands, depending on themes in the call
- University hospitals, geriatric "houses"
- ew are considering to build a cyberhospital in our university as clinical training center and testing facility for innovative technologies
- From SE presented at earlier workshop.
- Difficult to say. Companies are testing their products through clinical trials
- (to be confirmed): i. The Netherlands (University of Twente) ii. Portugal (Coimbra Eco System) iii. Belgium (Flanders Care)
- The Netherlands (University of Twente) Portugal (Coimbra Eco System) Belgium (Flanders Care)

4. How can it be ensured that the results/products tested and validated in a TEF based in one MS could have an impact in all Europe?

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- cross european advisory board
- through Joint Actions aiming at specific objectinves sharing the results of research through dedicated hubs
- It is important that the results are based on the real need of patients and clinicians. Needs should come from real world and then developers should adapt to that and validation in the real world environment it is important to have an iterative process
- Encourage cross-border collaboration via consortia
- Follow common European / global medical standards, involve more than one country / region in the testing process
- Similarly to what is done with federated learning, there should be federated testing, so that results are evaluated across different population types
- It is a must for a European coordination platform to ensure collaboration, communication

4. How can it be ensured that the results/products tested and validated in a TEF based in one MS could have an impact in all Europe?

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and sharing of best practices. Without this element, the European impact is in danger.

- Cross-validation in different countries will be needed in AI supporting physician decision making based on data
- TEFs should be run as consortia across Member States: this brings together data from many different physical locations, enables better assessment of AI algorithm generalisability, and may ensure that products tested at one TEF are transferrable to other locations. The more TEFs in a consortium, the better.
- It is highly necessary a proper European coordination to ensure collaboration, communication and sharing of best practices. Without this element, the European

4. How can it be ensured that the results/products tested and validated in a TEF based in one MS could have an impact in all Europe?

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- 1. impact is in danger and everything: access to research and SMEs (i.e., a researcher going to a TEF facility to another country); possibility for SMEs to test their products and services in real environment setting; sharing best practices in fields such as Robotics, AI, Active Assisted Living testing; help sustain the scalability of solutions in Europe; contribute to standardization and legal framework for Ai/Robotics based solutions).

5. What should a TEF consortium look like (what roles and expertise)?

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(1/2)

- Hospital, assistive care facilities, university (one ore more),
- Health Economics and humanities
- User organisations
- Public (regional bodies, hospitals) and private partners (industry- bothe smaller and larger companies)
- yes regions, but still keep EU focus
- Hosted by organizations which have strong ecosystems representation, like clusters
- Local/regional public health authorities
- Clinical expertise, technical expertise also from healthcare operative IT systems, regulatory and ethics, collaborative cross sectors (healthcare, govt, indutry, petient reps)
- Yes! Regions!
- apart from technical aspects and supporting services also ethical and legal aspects should be part of a TeF. Especially in health care!
- Infrastructure expertise in domain and technology regulatory affairs cross EU advisory board

5. What should a TEF consortium look like (what roles and expertise)?

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- Important roles: Hospital with IT infrastructure Regulatory service Patient Engagement
- Intranational coordinator Research Innovation actors Hospitals. Public bodies such as regions, health care orgs, municipalities, regulators. Investors.
- internal and international ethical committee could be interesting, too
- Main “reference” center managing hospital and research partners
- i. Research (centres and infrastructure for the actual testing). ii. Innovation actors (SMEs; regional agencies; incubators and start-ups). iii. Hospitals. iv. Public bodies such as regions, health care orgs, municipalities, regulators. v. Investors. vi. Supranational coordinator.

Do you think the TEFs should be run:

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as consortia, bringing together several facilities (each of them usually represents one physical location) from different countries,

92 %

or as individual facilities?

8 %

From previous consultations, we gathered that TEFs should allow for large-scale in-silico, in vitro, ex-vivo and in vivo testing, when relevant. How difficult and resource consuming would testing large-scale health datasets or registries be in your opinion

(1/4)

0 1 5

- the use cases to drive interopearb ility between domains is not clear
- Access and availability of quality large datasets, remove data siloes, increase interoperability, proper data infrastructure
- An internal super partes CRO could be interesting to have
- Integration of different data-sets over all domains
- is essential but challenging and very time-consuming.
- Federated leraning/testing to the rescue
- Here the TEFs should collaborate with the health data spaces!
- The high variability in sample size and feature distributions make it a challange
- Data privacy and security will be the bottleneck

From previous consultations, we gathered that TEFs should allow for large-scale in-silico, in vitro, ex-vivo and in vivo testing, when relevant. How difficult and resource consuming would testing large-scale health datasets or registries be in your opinion

(2/4)

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- Using health data requires 1) structured data entry - very immature in Europe 2) data infrastructures for healthcare facilities - some exist 3) harmonization and data quality improvement - lot of work
- Significantly...
- Main challenge is making Real World Patient Clinical Data available (GDPR and ethical issues need to be anlayzed)
- There is already work being done on health data sets for the whole EU, so if that work is done well, it could be easier than we think.
- The medical technology industry is particularly interested in the potential of in-silico testing of AI technologies in combination with

From previous consultations, we gathered that TEFs should allow for large-scale in-silico, in vitro, ex-vivo and in vivo testing, when relevant. How difficult and resource consuming would testing large-scale health datasets or registries be in your opinion

(3/4)

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modelling & simulation, but there is a concern that evidence produced by those in-silico models also gain regulatory acceptance.

- Large datasets do not come from one place. Several sites must join and expert support must be provided. RWD matter too.
- Regarding the type of data, stakeholders will need to have access to, demographic, clinical and biomedical-related data are the main ones; areas, such as mobility, imaging, behavioural aspects as well as environmental ones should also be looked at.

From previous consultations, we gathered that TEFs should allow for large-scale in-silico, in vitro, ex-vivo and in vivo testing, when relevant. How difficult and resource consuming would testing large-scale health datasets or registries be in your opinion

(4/4)

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The mechanism should aim to harmonise and pool together competencies and skills rather than isolating them. It is also noted the latest trends in collecting synthetic and pseudonymised data.

In case the TEFs will have the possibility to test large health datasets, how difficult/realistic do you see the process of obtaining the data – from a hospital, research institute, pharmaceutical company, insurance company, etc?

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(1/4)

- This requires a overall official policy/strategy for date reuse dealing wigth data harmonisation, etc..
- Delicate, difficult task GDPR etc.
- Depends on the source, on MS, on type of data (how sensitive/personal), MS legislation, cross-border etc?
- This is subject of EHDS and also of JA TEHDAS. Governance and other req. are neccssry.....
- unrelistic from Pharma/insurance it they are not fully involved somehow
- MedTech Europe recently highlighted some legal barriers to access to data: https://www.medtecheurope.org/resource-library/unlocking-the-full-benefits-of-health-data-recommendations-from-medtech-europe/
- We have some experience with

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using "simulated" data sets from a hospital system, available in the hospital testbed. It has worked well in a small scale. But integrating from different systems it is much more difficult.

- Extremely difficult. Why you dont include citizen generated data from health apps/gadgets.
- Clear data governance and mechanisms for data access and further processing across the EU
- It is possible if there is good focus (disease or patient group), general access is difficult. Hospitals and other data holders are key
- If the goal is to collect data, it is pretty unrealistic, federated methods are needed to ensure privacy and avoid the need of sharing the data itself
- quite difficult because of interoperablity issues

In case the TEFs will have the possibility to test large health datasets, how difficult/realistic do you see the process of obtaining the data – from a hospital, research institute, pharmaceutical company, insurance company, etc?

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and GDPR still open issues

- Ethical approval and access to (secondary) data is complex from a regulatory point of view.
- AI solutions for personalized health care and intelligent tools are scrutinized by data protection offices and ethical committees in terms of the benefits offered by artificial intelligence for health systems
- Depends. All types of data are needed. Each TEF must focus on some types of AI pructs, e.g. imaging. They cannot cover everything.
- indeed it overlaps. Efforts should be put into having a distributed data collection and data processing mechanism across Europe, combining

In case the TEFs will have the possibility to test large health datasets, how difficult/realistic do you see the process of obtaining the data – from a hospital, research institute, pharmaceutical company, insurance company, etc?

(4/4)

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local computing power (and storage, including personal private data) to levels of aggregation at regional, national and European level. The European Commission emphasised this need in several occasions (e. g.
in the communication on digital transformation of health and care); yet, a lot needs to be achieved, especially when it comes to governance model, data quality procedures and normalization/standardization

- depending on the nature of the tef, very easy or kinda hard

How to ensure equal access for all European providers, making TEFs a truly European resource? Should co-funding Member States help in dissemination about the TEFs?

(1/3)

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- Not only Member states but regional Governments can play an importatn tole
- Member state funding my gear activities to national / reqional implementations. University Hospitals are increasingly connected in Europe, which could help if supported
- A lot of efforts on making the concept understood to non experts
- Involve all relevant stakeholders of the healthcare ecosystem (hospitals, research centres, industry, etc). Member States can play an important role in promoting TEFs
- Should be integrated in the TEF consortium model, contract/agreement, interoperability.
- Interoperability is a must
- It is related to EU dimesionm of TEFs, it sneed to to be developed
- maybe some kind of system like

How to ensure equal access for all European providers, making TEFs a truly European resource? Should co-funding Member States help in dissemination about the TEFs?

(2/3)

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is done in the space industry to ensure the proper return on investment for ms

- interoperability and open data are
- A European coordination of existing Health/AI/Robotics/Active Assisted Living TEFs should be put in place to fully exploit the potential created at the national level and achieve greater impact at the European level. Strong dissemination, awareness raising and networking is also necessary across countries.
- Dissemination of capabilites, solutions developed, services offered are needed.
- What do you mean all European providers?
- It is not a real commitment, more political.
- Communication and

How to ensure equal access for all European providers, making TEFs a truly European resource? Should co-funding Member States help in dissemination about the TEFs?

(3/3)

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dissemination to create local/regional awareness is key

- Connection with EMA, notified bodies, MDR, etc.
- Yes, ensuring a pan-geographical involvement, not only from big cities but also from rural and smaller structures
- To ensure equal access to all European providers, a European coordination of existing Health/AI/Robotics/Active Assisted Living TEFs

should be put in place to fully exploit the potential created at national level and achieve greater impact at European level. And yes, if Member States are participating should also assist in the dissemination about the TEFs. More clarity should be provided on the matching funding (MS aor prvate investments)

How to ensure a high interest for using the facilities even if the users have to cover their own costs?

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- Synergy effects/federated access/one-stop-shop; supra-national/European perspective
- Trustworthy reports for proving MDR validation requirements
- Access to data and infrastructures, addedd values for beneficiries (eg. all care data in one place and standardised all over Eu countries)
- if the TEF serves to put solutions in the market, SMEs and companies will pay. It is important that the valorization chain continues. TEF should be link to investors who help get those validated ideas into the market. The TEF validation should accelerate bring the solution into market
- it needs to add value to the products/services and be clear about that
- focus on family and childcare healthcare - low birth rate is a sustainability problem - and we

How to ensure a high interest for using the facilities even if the users have to cover their own costs?

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(2/4)

do little to help families and working mother with providing on site and timely paediatric healthcare

- Focus, service attitude, low admin overhead visible to customers, access to close collaboration with real end-customers (healthcare providers and patients)
- That is norrmal, is not it? Particulalry healthcare is sensitive to this ...
- Adding services to the facilities
- Offer a clear added-value to the user (certification, validation, quality label, ...) which facilitates access to market throughout EU
- If services are valuable. And eventually embedded in public care or insurance coverage?
- promoting these initiatives as institutional ones
- Reasonable fees, perhaps with (initial) subventions. A sustainable business model is important. Also part of the project to develop.
- Providing access to networks they wouldn t easily have access to, as

How to ensure a high interest for using the facilities even if the users have to cover their own costs?

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well as connect with investors to give them possibility for further development.

- Quality of services delivered, value proposition for SMEs, added value of the TEFs
- By joining a TEF one would: internationalization its business exposure to an international scene access to knowledge; benefits from participation in new networks.
- Access to data, scalability
- It will depend on how well the TEF "supply" portfolio matches customers "demands"
- Depends on the quality of services they provide.
- Data has value. Access to data should come at some cost.
- Advanced, uniques solutions are available
- This is explainable by the internationalization potential of the offer: exposure to an international scene and set of stakeholders; access to best

How to ensure a high interest for using the facilities even if the users have to cover their own costs?

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(4/4)

practices and processes in other countries; possibility to enter new and greater markets; access to knowledge; benefits from participation in new networks.

Should the process of certification be part of the services offered by a TEF? Should the service of certification be centralised? How to work with certification authorities and existing certification bodies?

0 1 9

(1/4)

- Regional regulations applies for Personal and Protected Health Information . If a certification is to be provided, it might need to considere nuances
- nice to have, but it seems not realistic, even the test report of the required clinical investigation is good, maybe a easy access in convention with a notifid body
- TEF to prepare certification efforts (best practices, process support) but do not take a leading role in it, rather a guiding role
- Yes to help with harmonization of technical specifications and standards - what is realistic is the fact that it will be an iterative process, but we have to start somewhere
- This is the main question. It is impossible to overcome the

Should the process of certification be part of the services offered by a TEF? Should the service of certification be centralised? How to work with certification authorities and existing certification bodies?

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(2/4)

current practice. Not only CE marking but evidence for reimbursement

- This is not easy since in each EU Member state we have different processes I think. It could have a connection but not its function.
- Are we clear what we mean by certification? Including MDR assessment? And MDR risk classification
- TEF is not not and can not be a notifying body. The certification should be done by notified bodies, the TEF should comply to the requirements set in medial device directives
- Yes. Within the TEF. Also the service of getting funding for the next step in the way to the market. There should be expertise to validate in a way that certification is easily achieved
- Yes, I mean selected testing

Should the process of certification be part of the services offered by a TEF? Should the service of certification be centralised? How to work with certification authorities and existing certification bodies?

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for CE marking.of AI solutions

- 1. it depends of the consortium composition 2. better centralised for trust reasons 3. creating partnerships
- TEFs should support the path to certification but not replace the existing mechanisms (e.g. MDR notified bodies & regulatory services)
- Sand-boxes to 'modernise'/update the current practices of regulation and certifications would be an added-value.
- Maybe not really centralized but mutual recognition and acceptance of certificates is necessary
- Take into account existing frameworks as healthcare is already strictly regulated
- It would be important to define what we mean

Should the process of certification be part of the services offered by a TEF? Should the service of certification be centralised? How to work with certification authorities and existing certification bodies?

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(4/4)

by certification. This facilities can not become a bottleneck

- It should be offered by TEFs, not necessarily centralised
- The medical technology industry cautions against a role for TEFs in certification: they should not become regulatory bodies.
- One should be realistic in terms of regulatory and certification in the field. While certification and regulatory bodies are of outmost importance for the TEFs and should be part of the partnership, their way of working and mandate should be well defined, based on the specificities of eth FET domains and national realities

Should a TEF have a particular technological focus in, for instance, Robotics, or IoT, or particular health focus, such as Cancer or Active and Assisted Living?

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- Yes, It would increase the expertise in the area of choice and ensure access to the adequate population at Europena level like pediatrics
- They should be addressing a societal challengesuch as health and care/ageing society. A domain should be Assisted Living Technology, for instance
- Yes, but its too complex Q. Each TEF my have selected exertise in 1. kind of testing and 2. medical barnches
- I think application is more important - like pediatrics - and technology comes second.
- Relevance & focus come from applications and disease groups or patient groups. Interaction early on in the development process is needed, not only testing
- nodes in TEF can have different

Should a TEF have a particular technological focus in, for instance, Robotics, or IoT, or particular health focus, such as Cancer or Active and Assisted Living?

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expertise and complement each other, but as whole should be applicable for all healthcare uses.

- Application area, eg infectious diseases, cancer and chronic diseases, ageing population
- Application area - children, youth and families. So far we saw only geriatric care, but this is an opportunity to unburden unpaid work that is disproportionately allocated to working mothers in terms of housework and childcare, and use the opportunity redesign the balance
- If feasible, would be nice to go for different health areas in the life course
- Do you mean each of the six will have one focus? Can we cover all possible cases like this?
- Depends on the applications that will be submitted. Important

Should a TEF have a particular technological focus in, for instance, Robotics, or IoT, or particular health focus, such as Cancer or Active and Assisted Living?

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with clear criteria for the appointment of TEFs

- Could be; but not necessarily. There might be larer TEF covering more than one field. even more if the "consortium" model is accepted.
- Technical infrastructure can be specific but a health TEF should cover the whole health & care ecosystem (stakeholder involvement) around the TEF to be successful.
- no, In my view should be broad. On the other side a federated specialized TEF network could be interesting
- if TEF is a consortium not necessarily, research centers and university medical hospitals are multidisciplinary
- Link with the EHDS should be clarified
- I would go for the technological focus, as

Should a TEF have a particular technological focus in, for instance, Robotics, or IoT, or particular health focus, such as Cancer or Active and Assisted Living?

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this should be transversal to different health applications

- Yes, this must be a requirement. Cannot cover all
- TEFs should be addressing a societal challenge/domain such as health and care/ageing society rather than a technology. This is due to the rapid evolution of technology and because of the cross-cutting nature of AI and robotics. A domain should be Assisted Living Technology or AgeTech

What you consider to be particularly important in drawing up the call text in this area?

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(1/4)

- focus on identifioed gaps in the health system first (e.g. rehabilitation
- Allowing proposals to focus and propose what could make most impact in healthcare delivery and be implementable in hospitals. Two-stage approach could make sense.
- technical/clinical strong EU partnership
- Strong ethical and transparent spirit
- Focus domains and desired number of
- stakeholders + nature of stakeholders to be involved. Communication aspect and open access for whole EU.
- given complexity may be a two stage approach could be useful
- Clear criteria for the selection of TEFs, with transparency in the process. If specific topics are supposed to be included, this should be very clear too.
- cross border data exchange will be critical for such facilities,

What you consider to be particularly important in drawing up the call text in this area?

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therefore consider their strong collaboration with health data spaces initiativ.

- Make clear what would the responsibilities of the TEF will be.
- The consortia must cover a broad area of health
- integration of skills and participation of industry/regulatory institution, impact on healthcare innovation
- Cross-border dimension, eligibility of both smaller and larger companies
- End user participation ensured by participation of hospitals
- The European dimension must be much bigger. Keeping an eye on societal challenges such as ageing society
- Good dissemination, clear guidelines, if consortiums are required add a system for facilitating this
- link to AI regulation
- To include strategic focus on social reproductive health issues - low birth rate is a big threat to sustainability of our societies.
- EU dimension healthcare

What you consider to be particularly important in drawing up the call text in this area?

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need response

- How public and private partners can work together and what type of services the facilities should provide
- include deep examination of ethical and societal challenges derived from application in real life
- a. The European dimension must be strengthened. It is not by funding single national infrastructures that a European impact can be achieved. Also, access to and from different facilities will play a key-role. b. In some of the health and care areas it is not obvious to have already existing facilities, support to the development and positioning of the growing ones (in most of the cases associated or linked to the local/regional ecosystem) is necessary. Narrowing down the support to single entities (like hospitals, campuses, villages is limitative). indeed, access should be covered
- EU dimension

What you consider to be particularly important in drawing up the call text in this area?

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- Complementarity geographically

Which are the types of product, service and process innovations that could stem from the creation of such a TEF?

0 1 6

(1/2)

- access to novel tools, expertise and infrastructure
- Policy guidelines to introduce innovations in Halthcare
- Clinical training
- social equity
- Validation and testing services are very common in software engineering for space, aviation, railways. These would increase confidence of people on the systems and products developed
- A 21st century balanced way of family and work life balance - including the ability to have and financially support children at the beginning of peoples careers.
- System integration - systemic change of health and care processes
- In October 2020 Deloitte and MedTech Europe published the report The socio-economic impact of AI in healthcare: Addressing barriers

Which are the types of product, service and process innovations that could stem from the creation of such a TEF?

(2/2)

0 1 6

to adoption for new healthcare technologies in Europe which lists key AI technologies in healthcare and their potential impact.

- personalized medicine,
- All health technologies involving use of medical data
- Testing, quality, experise, evidence, etc.
- The best answer to this is that we could not tell - then it would be innovative!
- Age Tech services. New models for organization including digital technologies. Digital upskills
- Social aspects not just health services
- algorithms to be implemented in existing software or creating a new app
- AgeTech -related, assisted living technologies

What are the most appropriate Key Performance Indicators (KPIs) to assess the outcomes?

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(1/2)

- - services provided - new solutions in the market
- # of healthcare providers involved, companies involved, stakeholders involved, AI algorithms registered
- Sustainability - tackling big social and economic changes to the business model, Green targets - proportionate computing processing power .
- If possible - health outcome, individual and cohort/population. Non-bias
- caregiving metrics
- cost saving for healthcare systems
- Integration of existing infrastructure, products scaled-up
- Number of 'clients' using TEF infrastructure Number of digital health services deployed succesfully Number of involved health care stakeholders
- genderbalance
- AMount of attracted Investment after testing also outside Europe
- returning customers, certifications issued to

What are the most appropriate Key Performance Indicators (KPIs) to assess the outcomes?

(2/2)

0 1 8

market, number of ms involved

- nr of solutions used by citizens on a regular basis for more than one year
- patient experience measures
- NUmber of countries involved NUmber of solutions scaled up Types of technologies involved in on resolutions Number of citizens exposed
- Value for healthcare systems
- Cost-effectiveness of the solutions
- Number of products/services per year certified and reimbursed.
- For the medical technology industry we suggest as KPI: the number of products that have benefited from TEF access for development and/or validation that have been CE-marked under the MDR/IVDR.