

# Comments and suggestions to the WHO Public Consultation on the Draft Global Strategy on Digital Health

## 1. Purpose and Global Situation

Do the Purpose and Global Situation sections clearly outline the purpose of the Strategy and provide a clear background and Rationale?

**Answer:** NO

**If NO, please explain:**

Purpose section:

The section on ‘Purpose’ of the Global Strategy on Digital Health provides an essential **common definition**, extremely important for the purpose of a coordinated approach to digital health at global level. Rare Diseases International welcomes this definition as it includes a key notion by anchoring the concept of Digital Health to its practical application and to its results in terms of improved health outcomes. However, it is not clear if setting out this common definition, to be endorsed and appropriated by Member States through the adoption of the Global Strategy, is considered part of the purpose. If this is not the case, it may be considered to leave the matter of definition for the ‘Foreword’ or for an ‘Introduction’ section, and to focus on the purpose only in this section.

As the section stands, the purpose of the Global Strategy is not clearly defined. It is set out in the draft that the Strategy is “designed to help countries achieve the objective of advancing digital health”. It is said this will be done through a common vision, strategic objectives and a framework for action. However, the section itself does not provide any indication as to what these elements may be. It would be important to indicate in this section the scope of the strategy and the specific role that the WHO will play, as explained later on, as a repository of evidence and good practices and promoter of collaboration.

In addition, this draft section indicates that the Global Strategy “leads to concrete actions within the proposed timeframe of four years, from 2020 to 2024”. It would be appropriate to make a clear indication of whether these *concrete* actions refer to the ones described under the ‘Framework for action’ section. Another thing to note is that the actions under the Framework for action, as they stand, could qualify as **lines of action rather than concrete actions for 2020 – 2024**, and the wording could be modified in order to manage expectations of what the Global Strategy can achieve in the given timeframe.

### Global Situation section:

The section on the 'Global Situation' provides a good summary of the trends witnessed in the past decades and an accurate diagnosis of the main challenges. In particular, there is an important mention to the fact that "the successful adoption of Digital Health goes beyond the use of ICT to improve processes". Here, scalability, replicability, interoperability, security and accessibility are mentioned. However, there are **two additional elements** that should be included in this section:

- It is important to note that digital health projects are complex and often require **systemic change** which is too often neglected. It is important to **engage with users early on in the process**, not just to capture their needs in terms of the functionalities of a given system, but also to learn about how the system will impact and change the way they operate on a day to day basis.
- Another important dimension is that of **information and data governance**. **Privacy and ethics challenges** need to be addressed as an integral part of any digital health strategy. Data governance is often decided with a lack of transparency and in a fragmented way. For instance, reflection regarding the secondary use of data for additional purposes (from health care delivery to research for example) is often missing. Again, **involving all stakeholders and the patients, in particular**, in the definition and the management of the health data framework established is key to address this issue.

The section on the Global Situation also identifies as an important challenge the **lack of evidence regarding the impact** of Digital Health architectures, policies and strategies on Health Systems and on population health due to the infancy of the field and the time it may take to reliably measure impact from digital technologies. However, an additional element to consider is that sometimes measurements are solely focused on the *effectiveness* of a certain digital technology, when in fact, negative results may be reflecting **poor implementation or other aspects linked to the broader ecosystem such as regulatory challenges, misalignment of innovation and health policies, inadequate incentives, digital readiness of the workforce, etc.**

Finally, although the role of digital health in increasing access to sustainable and affordable health systems is mentioned, it would be important to emphasise that the use of disruptive technologies such as genetic sequencing, blockchain or artificial intelligence have the potential to deliver efficiencies throughout healthcare systems, with implications for health quality, cost and access. While the impact of the systemic use of such technologies still needs to be assessed, as mentioned in the draft Global Strategy, in the area of rare diseases these efficiencies are already being experimented and are showing results<sup>1</sup>. For example, the use of such technologies to improve access to accurate diagnosis for people affected by a rare disease, which is typically a year-long journey, could offer the opportunity to reduce the cost of diagnosis by establishing a more streamlined diagnosis process. As a way of example, deep machine learning technology, at global scale, has the potential to overcome the primary barrier to early and efficient recognition of a patient with a rare disease. As the cost for diagnosis is reduced, patient access is expanded, particularly across less mature healthcare systems where the traditional barriers to rare disease diagnosis are greater and de facto prevent access to suitable healthcare to a part of the population.

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<sup>1</sup> The *Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease* ([globalrareiseasecommission.com](http://globalrareiseasecommission.com)), has produced a [Report](#) on how disruptive health technologies can reduce the road to diagnosis for children affected by a rare disease, but also launched pilots to test in practice the recommended actions.

## 2. Vision Statement:

*Improve Health for everyone, everywhere by accelerating the adoption of appropriate Digital Health.*

Is the vision statement clear and comprehensive?

Answer: NO

If NO, please explain:

The vision statement as a sentence is clear and high-level enough to encompass all the elements that are detailed in the explanatory paragraph (page 6). However, this paragraph could be refined. Firstly, repeating here the notion of **digital technologies being a means to an end** would add coherence to the Global Strategy as a whole. The current mention in the paragraph to specific applications of digital technologies, such as those allowing people to manage their health more effectively or improve caregiver-patient communications, could be interpreted as techno-centric if this clarification is not reiterated.

Secondly, the following two additions could be made to the explanatory paragraph in order to clarify what *appropriate* Digital Health is:

- The vision of the Global Strategy should also be to encourage the development of **sound health data governance frameworks** for data sharing and processing.
- The vision of the Global Strategy should also clearly state the importance of developing **global normative guidance, technical assistance and advice** for Member States' shared challenges and needs, as well as promoting cross-country collaboration to address those challenges that cannot be addressed by countries in isolation. Typically, this type of actions are crucial to ensure access to healthcare to people living with rare diseases.

## 3. Strategic Objectives

SO 1. Engage Stakeholders on a Shared Global Agenda on Digital Health

SO 2. Build and Consolidate Global Digital Health Capacity that reflects National Needs

SO 3. Commit and Engage Stakeholders to advance Digital Health in every Country

SO 4. Improve Measurement, Monitoring, Research and Practice in Digital Health

Are these Strategic Objectives clear and comprehensive as a set?

Answer: NO

If NO, please explain:

It would be useful to include further clarification on how SO1 and SO3 complement each other. Engaging Member States towards a Global Digital Health Agenda goes in parallel to engaging them towards the advancement of Digital Health in their own country. Clarifying for instance how the WHO will support countries at national level and how this is different from engaging them in a shared global agenda on Digital Health may help make this

distinction more evident. In this regard, although the Strategic Objectives are not intended in sequential order and are to be developed in parallel, for ease of reading and comprehension, the order of the SOs could be switched to:

SO1: Engage Stakeholders on a shared global agenda on Digital Health

SO2: Commit and engage stakeholders to advance Digital Health in every country

SO3: Build and consolidate Digital Health capacity that reflects national needs

SO4: Improve measurement, monitoring, research and practice on Digital Health

In addition, it remains unclear why some specific areas of action are identified as common global needs under SO1 (“digital divide, digital health literacy, data privacy and security, data ownership rights and access, methods to support innovation that is effective, affordable, safe, scalable and sustainable”), whereas others qualify rather for country-specific advice under SO3 (“governance, value propositions, operational models, [...], interoperability, standards, infrastructure, human resources, systems and services”). Some of the areas under SO3 such as governance, operational models and standards could also be addressed as common needs under SO1. It would be good to either mention these as areas with potential for international collaboration, or to leave the specific areas of actions out of the section of Strategic Objectives.

### Are there additional strategic objectives needed to move the Global Strategy forward?

**Answer:** YES

**If YES, please explain:**

A new Strategic Objective on health data sharing would be extremely valuable. Aspects related to data quality and challenges to link different health datasets are preventing scaling digital technologies across high-income and LMIC. This specific objective would be distinct from the engagement of stakeholders towards a common global agenda or towards action at national level. It would engage stakeholders in addressing common challenges to data sharing and processing at global level, and cooperating to provide access to national datasets where there is a clear added value in collating data at global level. This includes the field of rare diseases, where due to the scattering of patient populations and the low prevalence of each disease in a given country, the sharing of data at international level is the only way of attaining a critical mass and addressing the rarity. This would allow for the generation of valuable knowledge for the improvement of research and healthcare practices that would otherwise not be possible at a national level. This in addition, would clearly align with the achievement of the health-related SDGs as the rare disease community embodies the motto of ‘leave no one behind’. Persons living with a rare disease are a vulnerable population that suffers from pauperization (SDG1), poor health (SDG3) and lack of inclusion in society (SDG 4, SDG 5, SDG 8, SDG 10). Persons affected encounter issues such as limited or scattered expertise, lack of diagnosis or misdiagnosis, and disproportionate out-of-pocket spending on health. In addition, people living with a rare disease are often lost in the system, having to visit different health, social and local services in a short period of time and interacting with actors that work in silos. A number of these issues could be attenuated through the establishment of global frameworks for data sharing that contribute to better healthcare.

The area of rare diseases is one that can hugely benefit from the increased biomedical information (propelled by ‘omic’ research - genomics, transcriptomics, metabolomics, proteomics, etc.) available to support scientific advances and inform healthcare decisions, as well as the technical capacity to produce and store large datasets, amidst decreasing technical costs, and the capacity to analyse this collective biomedical information. However, handling and sharing these ‘big data’ has significant implications as it raises challenging privacy and ethics questions on how to exploit its potential while protecting the interests of individual contributors and stakeholders<sup>2</sup>.

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1. <sup>2</sup> See Council of the European Union: Council conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health. *Official Journal of the European Union* 2017, C:443-449

As demonstrated by a number of studies conducted by EURORDIS-Rare diseases Europe, including a large quantitative survey on family perspectives on data sharing and data protection in research and healthcare settings (pending publication), rare disease patients are clearly supportive of data sharing initiatives to foster research and improve healthcare. However, rare disease patients' willingness to share their data does come with specific conditions and requirements in order to respect their privacy, choices and needs for information regarding the use of their data.

In the current landscape, making an effective use of the data is essential to ensure translation towards improvement in health outcomes. This is only possible through collective endeavours: the true potential of biomedical data can only be realised through its capacity to be combined and shared. Sharing and pooling data is one of the most important ways to ensure benefits for all, including patients, families, scientists, funders, health care providers and future users of the healthcare systems.

#### SO 1. Engage Stakeholders on a Shared Global Agenda on Digital Health

Is SO1 clear and comprehensive?

Answer: NO

If NO, please explain:

Strategic Objective 1 refers to a number of key areas for action which include: "digital divide, digital health literacy, data privacy and security, **data ownership rights and access**, methods to support innovation that is effective, affordable, safe, scalable and sustainable"; however, instead of 'data ownership rights and access' it would be more accurate to speak of **governance models for data capture and use**.

As detailed in the 'general comments' section of the questionnaire, it is not clear why and how these concrete areas have been identified as common challenges to be addressed as part of the global agenda on Digital Health, when other areas delineated in SO3 (standards, operational models, and implementation, for instance) could also fall under this category. It would be useful to specify the selection criteria and the references used if there has been such a systematic categorisation of areas of action fitting in either SO1 or SO3.

#### SO 2. Build and Consolidate Global Digital Health Capacity that reflects National Needs

Is SO2 clear and comprehensive?

Answer: NO

If NO, please explain:

The overall aim of SO2 to build national capacities to deliver a Digital Health Strategy is clear. However, apart from the important seven components of the WHO/ITU National eHealth Strategy Toolkit and the "foundational capacities such as governance, leadership, advocacy and other organizational resources", there are also other areas where capacity-building is essential, namely:

- **Ethics**
- **Evaluation methodologies**

- **Implementation/change management**

**SO 3. Commit and Engage Stakeholders to advance Digital Health in every Country**

Is SO3 clear and comprehensive?

**Answer:** NO

**If NO, please explain:**

It would provide clarity to specify who the stakeholders are. In SO2 the stakeholders refer to not just countries but also a “broad range of international and global stakeholders”. It would be useful to know if this also applies in SO3 or if in this case ‘stakeholders’ refers solely to Member States. Still, more broadly, detailing the sorts of ‘international and global stakeholders’ would also help to the comprehension of the Strategic Objectives.

**SO 4. Improve Measurement, Monitoring, Research and Practice in Digital Health**

Is SO4 clear and comprehensive?

**Answer:** Yes

Additional comments on Strategic Objectives:

**4. Framework for Action:**

1. COMMIT – encourage countries and involve stakeholders to commit to the Digital Health Strategy
2. CATALYSE – create an environment and process that will facilitate and encourage collaboration
3. MEASURE – create processes for monitoring and evaluation of the Strategy
4. INCREMENT AND ITERATE – take a new cycle of actions based on what has been experiences, measures and learned

Will the proposed “Framework for Action” deliver on the implementation of the Strategy?

**Answer:** NO

**If NO, please explain:** See the comments provided below in the different individual sections of the questionnaire.

Does the proposed “Framework for Action” clearly outline actions required by WHO, countries and stakeholders for the Strategy to succeed?

**Answer:** NO

**If NO, please explain:**

Firstly, there is a lack of clarity as to the types of actors that are encompassed in the category of ‘stakeholders’. In some sections of the text countries seem to be included into the ‘stakeholder’ category as in SO1 and SO3 (pages 6 & 7), however, in other instances there is a distinction between ‘countries and stakeholders’ (page 9). Still, in other instances, specific types of stakeholders are mentioned (e.g. “funding agencies” or “other organisations of

the United Nations System” page 9). Secondly, there is also a lack of consistency in describing the actions that are to be taken by the WHO and those that are to be taken by other actors. For instance, within COMMIT 8.1.1 ‘create a roadmap for attracting and engaging countries and stakeholders’, there is no mention to the actor leading on this action. However, within CATALYSE 8.2.1 ‘identify and qualify needs and offers’, there is a clear mention to WHO being the actor to lead this action. All in all, there is an issue of consistency in the text that makes it difficult to clearly identify the actions to be carried by each actor. A different structure where actions are consistently divided around these categories (WHO, countries and stakeholders) with additional sections for joint actions could be helpful.

Please provide any specific comments on the proposed action lines below.

#### 1. COMMIT

- Create a roadmap for attracting countries and stakeholders
- Identify, approach and engage “champion” countries

This section of the text is not completely clear on whether the roadmap for attracting countries and stakeholders will be created by the WHO and other organisations of the United Nations system only or whether this will be co-created with countries and other stakeholders. It would be important to develop it in a spirit of co-creation so as to ensure buy-in from all partners essential to the achievement of the Global Strategy.

Identifying ‘champion’ countries willing to share the experience is a suitable action as long as this is done in a systematic way. There are a high numbers of good practices as well as failures that can be shared from different countries; however, a challenging and often underestimated task is how to transform these into valuable and actionable lessons for other countries.

Last but not least, as part of this exercise, it would be important to clarify the interplay between the private sector, notably the developers and owners of digital technologies, and government as guarantors of equitable and universal access to healthcare for all. While innovation and flexibility of the private sector must be harnessed in this space, as they bring about novel technological solutions with potential for significantly improved healthcare access and health outcomes, it is essential to factor in the risk that the ownership of platforms and technologies may lead to the risk of vendor “lock-in” if a few or a single private player assumes a large role within a country’s health system. It is therefore of crucial importance that early engagement and dialogue is established with technology developers and owners, so that national and international strategies for digital health are shaped with the patient interest at heart and equitable access to healthcare for all, while recognizing the legitimate expectation that the private sector would have on reasonable return on investment. Government at all levels (sub-national, national or international) has a role to play to secure that the general interest is pursued and the right mechanisms and platforms of dialogue are established.

#### 2. CATALYSE

- Identify and qualify needs and offers
- Match needs and offers
- Develop a roadmap for providing technical support and guidance
- Accelerate and sustain progress

The approach to combine COMMIT and CATALYSE actions relies heavily on the WHO’s ability to mobilise stakeholders and countries. This is of course one of the strengths of the WHO and history proves its capacities as an enabler; however, with such a revolutionary topic, which can create polarized views, there is a risk that mobilizing stakeholders may not be as straightforward as predicted. This could result in the successful creation of

a global knowledge hub on Digital Health, but not yet achieve the step of development of specific guidance and support for Member States. In turn, this would mean that the actions planned may not deliver on the Strategic Objectives set out in the Global Strategy in the time-frame provided.

Moreover, it would be important to specify that the role of WHO as catalyzer, together with relevant stakeholders, is as important in sustaining countries to develop their national digital strategies as it is in promoting and implementing cross-country collaboration in digital health. Such cross-country collaboration is uniquely supported by digital health technologies in areas of scarce knowledge and expertise, such as in the field of rare and complex diseases. Digital health technologies can improve the coordination of care and facilitate the collaboration of experts, but they can also be instrumental in the implementation of integrated care pathways, accelerating research, measuring quality and outcomes, delivering personalized care and enabling patient empowerment and engagement. The possibilities of International Reference Networks for rare and complex diseases, for example, are within reach thanks to information technologies, their higher capacities and lower costs. Drawing from the European example, virtual networks of clinicians will soon be in a position to adopt common standards with regards to data collection and interoperability.

### 3. MEASURE

- Assess Strategy and framework for action effectiveness
- Technological trend monitoring

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### 4. INCREMENT AND ITERATE

- Propose, exercise and refine
- Optimise the Collaboration Network

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#### Additional comments on Framework for Action:

The Global Strategy sets out very high-level and ambitious Strategic Objectives to be carried out in parallel; however, there is little mention to the **funding mechanisms** that are to be used. There is one mention to the role that funding agencies could play (page 9) as well as a mention to the need to “secure the funds and other resources for the first wave of actions” (page 14), but it would be useful to go into more detail into the sorts of instruments and external resources that could be mobilized.

Another key element that should be given more visibility in the Framework for Action is the question of **governance**. There is a lack of clarity on the mechanisms through which the Global Strategy is going to be governed and the ways in which experts and stakeholders are going to be engaged on a regular basis. It is acknowledged in the document that “a major challenge for the Strategy is its reliance on a coordinated and independent network of committed stakeholders” and that there is a need to continuously monitor and assess that activities are coordinated and they align with the Strategy (page 13). It is not mentioned how this process will be achieved. A suggestion is to create of a **coordinating committee**, facilitated by the WHO, and with appointed representatives from different stakeholder categories.

## 5. Proposed Roles:

Will the proposed roles for WHO, relevant stakeholders and countries help to deliver on the Strategy?

**Answer:** NO

**If NO, please explain:**

As mentioned earlier on in the questionnaire, there is firstly a matter of consistency in the use of terms to be addressed in the document for a better comprehension of the categories of 'stakeholders' mentioned. Secondly, as also mentioned above, the current Framework for Action and Proposed Roles rely very heavily on the capacities of the WHO to engage stakeholders and may be too ambitious for the time-frame provided.

### Additional comments on Proposed Roles:

There is a very important notion in the text about **encouraging healthy individuals, patients and their organisations** to "collaborate with the international community to *bring in the perspective* from patients, communities, families and caregivers, *advocate in favor of Digital Health*, as well as *disseminate best practices and successful examples* of digital health initiatives" (page 13, emphasis added). Collaboration with the beneficiaries is indeed essential to ensure buy-in and the development of a strategy that addresses the needs of and has positive outcomes for the target population. In fact, this can have an impact at various levels: the micro (patient) level through improved health, greater satisfaction with treatment option, better quality of life and psychological state; the macro (community) level through improved quality of health and social services and a design of interventions responding better to needs; and the policy level through improved policy prioritisation, design, and cost-effectiveness. This is something that could be more explicitly referred to in the text. In addition, an important element to note is that *advocacy* and *dissemination* are not the only dimensions in which the collaboration with beneficiaries should be considered. Real **beneficiary (patient) empowerment and engagement** goes beyond this and should encompass a range of **official mechanisms** to make sure that they are also part of the governance, through their involvement in Steering Committees or equivalent bodies overseeing the implementation and/or the monitoring/evaluation of the Global Strategy.