CATALYST DIALOGUE ON DIGITAL HEALTH DATA GOVERNANCE

A new global framework on health data governance?

Insights from a debate on ways to strengthen privacy and human rights in digital health.

Emerging suggestions

The following suggestions for German policy-makers and parliamentarians surfaced over the course of this Catalyst Dialogue:

→ **Champion a rights-based approach to health data governance globally** that:
  - **Enables data sharing** for the benefit of the individual and for public health while **safeguarding the right to privacy.**
  - **Promotes transparency and equity** in data collection, management and use.
  - **Prevents and actively works against bias and discrimination** in data and in algorithms that process them.
  - **Empowers individuals** to know their rights, own their data and decide about their use while ensuring that the burden of accountability does not fall on them but remains with the respective duty bearer.

→ **Offer technical and financial cooperation to partner countries to support them in strengthening their legislative frameworks** to incorporate good health data governance, working with parliamentarians and civil society, based on Germany's experience with robust privacy and data protection rights.

→ **Work with government agencies mandated to monitor implementation and enforce compliance with health data governance rules**, such as the data protection commissions that exist in some countries, to ensure that normative frameworks translate into practical changes on the ground.

→ **Ensure good health data governance in German-supported projects** by requiring organisations that operate with German funding to implement a rights-based and human-centred approach and to adhere to the existing legal frameworks on privacy and human rights in their respective contexts.

→ **Nurture a vibrant and diverse landscape of civil society actors to hold governments accountable and to advocate** for a rights-based approach to digital health.

Catalyst Dialogue participants:

- **Frances Baaba da-Costa Vroom,** President, Pan African Health Informatics Association
- **Alexandrine Pirlot de Corbion,** Director of Strategy, Privacy International, with inputs from Tom West, Legal Officer, in the bilateral interview
- **Christoph Benn,** Director for Global Health Diplomacy, Joep Lange Institute; President, Transform Health; Board Chair, The International Digital Health and AI Research Collaborative (I-DAIR)
- **Christian Möhlen,** former Global Head of Legal Affairs, Kry International

Why a Catalyst Dialogue on health data governance?

Digital health technologies have the power to accelerate health equity by making health systems stronger, more effective and more responsive to the needs of the populations they serve. These innovations are driven by reliable, high-quality data.

The challenge today is not a shortage of data, but the ability of governments, corporations and individuals to understand and use the available information for the greatest benefit of all, while protecting people's privacy and rights, and ensuring that scientific and ethical standards are met.

The question has been raised whether the global community needs a framework to ensure the safe and ethical use of health data. Several organisations have called for a common set of rules akin to a 'social contract'. Such an agreement would need to strike a balance between, on the one hand, the full use of data for development and on the other hand the protection of security, privacy, and human rights. It would likewise need to ensure a balance between use of data for commercial interests and the interest of the public good. Transform Health, a global civil society coalition, has proposed such a framework: the Health Data Governance Principles.

To inform the German government's position on whether one shared global framework would be necessary – and what general measures could be taken to strengthen health data governance, the Global Health Hub Germany and Healthy DEvelopments convened a high-level 'Catalyst Dialogue'. Co-sponsored by the German Federal Ministries of Health and of Economic Cooperation and Development, it brought together four distinguished representatives of academia, development cooperation, foundations and the private sector. Participants initially took part in individual interviews and then gathered for a virtual discussion.

The objective of this paper is to share the diverse perspectives of the Catalyst Dialogue participants on this issue. Rather than presenting a consensual statement, the document closely follows the discourse as it unfolded. It illustrates policy-relevant positions and presents opposing and sometimes even contradictory perspectives, all of which promise to enrich Germany's policy dialogue on health data governance.

This brief is structured as follows: It first summarises the panellists' views on how health data are currently governed and why change might be needed. A short synopsis of the proposal for a new health data governance framework – the Health Data Governance Principles – is provided. The paper then traces the discussion and presents arguments for and against a global framework and reflections on what measures need to be taken to strengthen health data governance. The final section outlines steps that Germany could take to support partners' efforts in this important area.

How do Catalyst Dialogues work?

Catalyst Dialogues focus on one overarching question, combining virtual debates and individual interviews governed by the Chatham House Rule. This gives discussants the space for open and frank conversations 'on the record' while protecting the identities and affiliations of the speakers. Quotes cited in this paper are attributed to individual Dialogue participants with their express permission.

How are health data currently governed?

The Catalyst Dialogue participants first reflected on how health data are currently governed to understand whether and what type of changes might be necessary.

Diverse rules and regulations make data protection difficult

The Dialogue participants were in agreement that there are no common global standards for the generation and use of health data. Every country has its own governance framework, and regulations are patchy in many contexts, which makes effective data protection difficult.

> *"A lot of innovations in the health sector are being deployed without considering a rights-based approach. This creates huge risks when thinking about what happens to the data: How is it being collected, who is going to end up using it, particularly in contexts where there isn't a legal framework?'*
>
> Alexandrine Pirlot de Corbion

The panellists shared a general concern regarding possible infringements of data protection, privacy and human rights. They pointed out that the risk of data being disclosed to third parties – without the individuals' knowledge or consent – does not only stem from illicit practices, such as companies selling data or hackers stealing information. Authoritarian governments have been known to access their citizens' personal information, including individuals' communication- and health-related data, without informing them, let alone asking for permission. These regimes may then use these data to target, discriminate against or otherwise constrain the civil liberties of individuals or groups, subverting their own responsibility for ensuring the human rights of their citizens, including their rights to health and to privacy.

The burden of assessing possible data protection risks should not fall on the individual

One Catalyst Dialogue participant argued that the digital transformation of health empowers the individual in several different ways. For example, the introduction of digital patient files allows users themselves to access their medical history. Up to now, this was locked away in their general practitioner’s filing cabinet. Looking beyond health service providers, every owner of a wearable device that generates health-related data, such as a smart watch, can decide to share their data with an app provider and get personalised suggestions for a healthier lifestyle.

> *“ Digitalising the health sector empowers the individual to finally have access to their data which previously remained only with the family doctor or was scattered between doctors and hospitals. With digital data, there is a massive shift towards helping people take care of themselves.’*
>
> Christian Möhlen

Another panellist cautioned that such digital health applications carry data protection risks that users may not be aware of. In this person’s view, the burden of data protection should not be shifted to the individual. The first panellist responded that it is in the digital health enterprises’ own commercial interest to fully ensure the protection of their customers’ health data.

> *“ We are worried that the current approach to “empowering individuals” ends up putting the burden on the individual to protect their data when that responsibility and accountability should be with the data controller.’*
>
> Alexandrine Pirlot de Corbion

> *“ I wouldn’t underestimate the market effect. The worst thing that can happen to you as a company in the healthcare space is if your patient data is leaked. Serving the patient’s interests also serves your business interest.’*
>
> Christian Möhlen

The lack of common standards limits interoperability and competition

Several Dialogue participants indicated that the absence of common health data standards and regulations constrains how health data sets and digital solutions can be combined and used across contexts. This is a challenge that BMZ-commissioned projects have been working on for some time, including through the Health Data Collaborative. One panellist emphasised that, if health data could be aggregated on a larger scale while governed by a common framework, the scope for research and digital health innovations would increase exponentially.

Another panellist was concerned that the current fragmentation of health data governance constrains competition between developers of digital solutions, playing into the hands of a few powerful corporations. This is because only the biggest and best-resourced companies can afford to deal with countless different legal and administrative requirements across jurisdictions.

> *Small companies or organisations can't afford to seek certification under 200 different rules in different jurisdictions, so it will always be the very big players who end up controlling things.'*
>
> Christian Möhlen

The power of large corporations to access and exploit big health data must be kept in check

Discussants found that a concentration of power is already happening. The vastly increased availability of data, combined with the latest advances in technology and artificial intelligence (AI), has enabled a small number of private and public players to gain outsized influence over how health data are generated and used, demanding a new approach to how this space is governed globally.

One participant referred to a recent Global Research Map of Digital Health and AI which shows that the two global heavyweights that lead strategic research and investments in AI and health are found in Silicon Valley – driven by private entrepreneurship – and in China, where this is a government-controlled agenda.

Both types of players have access to vast data sets, capacity and resources, but for different reasons. The data they control and the systems that process them transcend borders, challenging the ability of national governments to enforce data protection, privacy and human rights.

> *Google, Amazon or Microsoft have access to the data of billions of people. Although these companies are not health organisations, they invest in AI for health, driven by commercial interests that are very, very powerful. The challenge is how to regulate this.'*
>
> Christoph Benn

Against this background, several panellists advocated a health data governance agreement that would be globally binding and equally effective for all relevant players, from governments to multinational corporations to small non-governmental organisations. The Dialogue participants acknowledged that establishing such a set of rules would require giving a diverse range of actors, including states, private companies and civil society, a seat at the table.

Power imbalances between North and South create tensions over data ownership and use

The discussion highlighted another power dynamic that shapes health data governance: Some Catalyst Dialogue participants pointed out that the uneven distribution of influence between development assistance agencies from the Global North and their partners in the Global South can create conflicts over who owns and controls health data.

> *“ Having ownership of the health data is important because we can analyse issues that are important to us and develop policies which are relevant to us. We shouldn’t have to ask permission to use our own data.’*
>
> Frances Baaba da-Costa Vroom

According to one panellist, it is not uncommon for international partners to introduce specific digital health applications into their cooperation with low- and lower middle-income countries. In such situations, the partner countries find it difficult to say ‘no’ or request that alternatives be explored because the cooperation and funding may be tied to the use of the tool proposed by the development partner – regardless of whether it has been shown to be the best digital solution for the task at hand.

Furthermore, participants indicated that some partners use their power to control and micromanage the digital health projects they support, the data they generate and how they are used, thereby undermining local ownership. One panellist mentioned the roll-out of the Surveillance Outbreak Response Management and Analysis System (SORMAS) in Ghana, promoted by Germany, as an example of an externally supported software solution, where national data ended up being hosted and managed by a foreign company. This approach stood in contrast with Ghana’s District Health Information Management System (DHIMS) II, a locally hosted and managed version of the internationally developed DHIS2 open-source software which is used in all but four African countries. However, the participant mentioned that the SORMAS case may also have emerged as an issue of local leadership not having caught on to the importance of appropriate governance arrangements.

> *“ Leadership within the country is important to ensure we have ownership of digital health solutions, but many people in the health sector and in government don’t fully understand technology, digital health and the consequences and the pitfalls that come with them.’*
>
> Frances Baaba da-Costa Vroom

In light of these concerns over the currently inadequate governance arrangements and the risks for health data protection, the Catalyst Dialogue participants reflected on the question of whether a common global framework is necessary – or what other measures could be introduced to strengthen health data governance.

The Health Data Governance Principles: basis for a new global framework?

Two panellists who are engaged in the global civil society coalition Transform Health pointed to their ongoing work on the Health Data Governance Principles as a practical and promising approach to move towards a common global framework. They explained that, to develop the Principles, Transform Health initiated a bottom-up consultation involving exchanges with 130 organisations across all world regions. Participants included civil society, governments, international organisations, research institutes and the private sector.

The coalition arrived at eight principles that seek to balance individual and collective perspectives across three objectives.

> *You cannot just rely on governments and member states, which is what WHO is good at, to govern digital health data globally. A network like Transform Health can convene the broadest possible coalition involving all actors that need to be on board with this.’*
>
> Christoph Benn

Health Data Governance Principles

Protect People

- *Protect individuals and communities*
- *Build trust in data systems*
- *Ensure data security*

Promote Health Value

- *Enhance health systems and services*
- *Promote data sharing and interoperability*
- *Facilitate innovation using health data*

Prioritise Equity

- *Promote equitable benefits from health data*
- *Establish data rights and ownership*

Source:
www.healthdataprinciples.org/principles

While the Principles have not yet been adopted as a global governance framework, according to the two panellists the next major milestone for Transform Health and its partners will be to seek endorsement from the World Health Assembly and ultimately adoption of the Health Data Governance Principles by all actors involved in digital health and data management, including civil society, the private sector, and governments.

But is such a framework really needed?

Arguments against a new global framework

Existing norms are sufficient but require political will to be implemented

Not all participants were in agreement with the proposal of a new global framework for health data governance. One panellist found new standards or rules unnecessary because of the plethora of existing international and national commitments and regulatory frameworks on human rights, health, privacy and data protection. This participant pointed out that states have obligations that derive from international treaties and covenants, and across different countries national legislation provides for human rights, including the right to health and the right to privacy, as they derive from international human rights standards and principles.

> *'Instead of calling for* ***more*** *frameworks, we should first utilise the* ***existing*** *frameworks. If they are not sufficient or need improvement, we should reinforce and strengthen them.'*
>
> Alexandrine Pirlot de Corbion

Instead of introducing yet another set of norms, this panellist felt the attention of governments and civil society should be on implementing the existing obligations under the prevailing laws and agreements. The participant pointed to a recent report by the UN Special Rapporteur on the Right to Health on digital innovation which reiterated concerns about the potential of digital technologies to perpetuate sexism, racism and other forms of discrimination, concluding that the report's core message is 'that there is lack of political will to adopt a rights-based approach to the use of new technologies in the health sector'.

A new global framework risks undermining existing, more stringent norms

> *'We are wary of calling for an international or global framework because, if we reopen these discussions about the existing safeguards, we might end up with a global treaty or an international convention that might water down the existing safeguards.'*
>
> Alexandrine Pirlot de Corbion

The same panellist voiced a concern that introducing a new global framework on health data governance would not only distract from implementing existing obligations, but might end up codifying merely 'what everyone can agree on', which would lower the bar further in some jurisdictions. For example, the European Union's General Data Protection Regulation (GDPR), sometimes referred to as the 'gold standard' of privacy laws, merely codifies a minimum standard that aligns with international human rights recommendations, but might fall behind the national legislation that some countries have already adopted.

The proposal on the table offers nothing new

The panellist found that the added value of the Health Data Governance Principles as basis for a new governance framework is unclear, mainly because they do not encompass novel ideas that are not already contained in existing norms.

> *‘None of these principles are new. They are all encoded either in national or international human rights law and part of a rights-based approach to the use of new technology that we are advocating for. There is no point in reinventing the wheel.’*
>
> Alexandrine Pirlot de Corbion

The participant contended that the Principles could serve for awareness raising, specifically within a health context, but that ultimately something more robust that can be enforced and that is legally binding would be required. For this, the panellist argued that international and national norms and standards are already in place.

Arguments in favour of a global framework for health data governance

The majority of the Catalyst Dialogue participants underscored the importance of working towards a global framework for health data governance. Their overall perspective is that this will make it possible to fully reap the benefits of digital health while addressing the current governance shortcomings outlined above.

Global rules are needed to guide the digital transformation of health

One panellist pointed to a recent policy brief by Transform Health to summarise why a global governance framework for health data is necessary. The study finds that health data in different regions and jurisdictions continue to be governed by a range of conflicting instruments, policies and norms. These legal provisions are not updated on a regular enough basis to keep up with the pace of innovation. Therefore, important issues around the generation and use of health data, such as the deployment of AI, remain practically unregulated.

> *‘The world is falling behind in achieving comprehensive primary health care, universal health coverage and Sustainable Development Goal 3. The digital transformation is key to achieving all these agreed international goals, and we need a global framework to guide this process.’*
>
> Christoph Benn

These participants argued that an overarching international framework is needed to guide the digital transformation of health taking place all over the world. The objective is to establish ethical ground rules for using and managing health data within and between countries in ways that support universal health coverage (UHC) and that do not undermine equity or human rights.

> *The key is that we are approaching this from a* ***global*** *perspective. Yes, there are national laws and some regional frameworks. But the digital transformation in health affects all countries around the world, but not all of them have a framework that steers the digital transformation without jeopardising human rights, privacy, equity and transparency.’*
>
> Christoph Benn

Although national legislation and regional frameworks exist that are relevant to digital health, privacy and human rights, the rapid digital transformation of health – super-charged by AI – is happening almost everywhere but not all countries are in a position to steer this process effectively.

A common framework strengthens interoperability and limits the concentration of power

These panellists argued that common governance rules also create an enabling environment for common standards to emerge. These entail multiple benefits: An accepted way of generating, storing and using data establishes interoperability between jurisdictions and platforms, thus levelling the playing field and removing barriers to market entry for smaller players, fostering diversity and innovation. Once standards have reached a certain acceptance threshold, they lend legitimacy to actors and activities that adhere to them and discourage non-compliant behaviour. Eventually, standards become self-reinforcing ecosystems. All actors have an interest in complying, because end-users tend to shun products or services perceived to be outliers. This is evident from examples ranging from video recorders to mobile phone operating systems.

> *A common normative framework and standardisation would have huge merits from a public health perspective. It enables competition from smaller companies and organisations and ultimately strengthens quality.’*
>
> Christian Möhlen

By establishing common principles, a global framework for health data governance would also counter current trends of concentrating power in the hands of a limited number of major corporations and non-democratic governments. In fact, collaboration across North-South and public-private divides was found by these participants to be the only way in which to avoid an oligopoly of the currently dominant forces in AI research and investment for health: Silicon Valley and China.

> *Smaller countries, and even mid-sized countries like Germany, find it difficult to participate and compete in this AI and research market for health if they don’t collaborate with others, pooling data, expertise and financial resources.’*
>
> Christoph Benn

Shared global norms will promote health data equity

The Dialogue participants in favour of a global framework also argued that it would strengthen equity in health data sharing and usage and help manage the current tensions over ownership of health information, as outlined above.

> *‘That global framework can make an impact on many levels, for example, the relationship between partners in the North and South and the power balance between doctor and patient.’*
>
> Frances Baaba da-Costa Vroom

If governments, corporations and civil society are aware of and subscribe to common principles, they can hold each other accountable about how data is generated, what is shared, who can use it and for which purposes.

More consistent and transparent data sharing strengthens global disease surveillance and pandemic preparedness and response – issues of critical importance, as was learned during the COVID-19 pandemic.

> *‘Companies are not organised like governments with laws and regulations. That’s why they need principles they can adhere to, to make their research and investments more legitimate.’*
>
> Christoph Benn

The Principles can align governments, private sector and civil society behind health data governance

The two panellists associated with Transform Health argued that the Health Data Governance Principles would be an important starting point for a common understanding of what health data governance should accomplish. Their broad-based adoption by a diverse coalition of government, private sector and civil society actors would legitimise the resulting ‘social contract’ and ensure that everyone adheres to them.

> *‘If the Principles are incorporated into national strategies and policies, they can trickle down and affect even the lowest healthcare delivery level.’*
>
> Christoph Benn

Once adopted, the Principles would need to be adapted to each specific country context. This would help national lawmakers, data protection agencies, health institutions, companies, civil society and citizens to understand and realise their rights and obligations.

What practical measures can be taken to strengthen health data governance?

Despite diverging views on the need to establish a global health data governance framework, all Catalyst Dialogue participants agreed that health data governance needs to be strengthened at all levels, from the global to the local. They proposed several courses of action, most of which align with the approaches implied by the Health Data Governance Principles.

Adopt a rights-based approach

The participants converged on a set of key tenets for better governance of health data, whether pursued through a new global framework or by more stringently implementing existing norms and policies.

1. Adopt a rights-based approach for the governance of digital health data.
2. Enable health data sharing for the benefit of the individual and for public health while safeguarding the right to privacy.
3. Promote transparency and equity in data collection, management and use.
4. Prevent and actively work against bias and discrimination in data and in algorithms that process them.
5. Empower individuals to know their rights, own their data and decide on their use, while ensuring that the burden of assessing potential risks and guarding against them does not fall on the individual but remains with the respective duty bearer, i.e. the data controller and ultimately the government.

Support governments in reviewing and strengthening their legal frameworks

All panellists emphasised that it is important for governments to invest in having a strong legal framework. In democracies, parliaments set the legislative boundaries for the digital transformation of health systems and for how the right to privacy, among other rights, will be implemented.

Lawmakers need information on gaps in legislation and on the need for new or different forms of regulation, and must be able to identify opportunities to nurture rights-based digital health.

> *“From a private sector perspective, I want to have a government that defines the ethical framework for how we do business.’*
>
> Christian Möhlen

Given the complexity of health data governance and the use of digital technologies, panellists identified an opportunity for organisations active in this space to engage and advocate with parliamentarians. Supplying information, possibly paired with technical expertise, about the opportunities and risks of digital health and the importance of good health data governance can support lawmakers in introducing or strengthening regulations, as necessary.

Enable civil society to advocate and educate for broad-based awareness

The Dialogue participants agreed that an active civil society is essential for holding governments to account. However, the panellists emphasised that in some low- and lower- middle-income countries diverse stakeholder voices are unlikely to emerge and sustain themselves without financial and some technical support. Civil society organisations (CSOs) could benefit from better access to information about what constitutes good health data governance to allow them to effectively fulfil their accountability function.

> *‘There must be a mind shift in the general population. We need advocacy and education to allow people to understand what their data are going to be used for. I must feel that I have the right and I have the power to ask those questions.’*
>
> Frances Baaba da-Costa Vroom

Beyond accountability-focused CSOs, one panellist underscored the importance of promoting broadly based awareness and acceptance of privacy and data protection among the wider population. Ultimately, better data protection literacy will help all individuals know their rights to privacy and data protection. This participant added that such education and awareness campaigns must employ means that are appropriate to the respective country or community setting, particularly regarding the language and the dissemination channels used.

Nurture the capacity to operationalise good health data governance

At the implementation level, almost any organisation can find itself in the pivotal position of being a data controller, defined in the GDPR as the entity that ‘determines the purposes for which and the means by which personal data is processed’. The panellists suggested supporting these key actors to ensure they are aware of, understand, adopt and fully implement a rights-based and human-centred approach to health data governance. This includes academia and research institutions, businesses, CSOs and, of course, health facilities.

> *‘We have found that many humanitarian organisations want to be able to include things like capacity building in their budgets to understand privacy, human rights implications, do risk assessments and implement mitigation strategies for their programmes.’*
>
> Alexandrine Pirlot de Corbion

Likewise, one panellist was convinced that government agencies with a responsibility to monitor implementation and enforce compliance, such as the data protection commissions that exist in some countries, would benefit from some technical and financial assistance to review and strengthen their practices in light of the key tenets for health data governance outlined above.

Encourage development of and investment in national digital health strategies

One participant underscored that many countries, have already developed digital health strategies and know what it would cost to implement them. However, many others have not yet done so, and those countries that have a digital health strategy might have gaps or inequities in their plans, leaving out certain regions or segments of the population. For this reason, the panellist considered it essential that all countries engage in the discussion around good health data governance. Technical and financial assistance can support governments to calibrate their normative frameworks and identify investments so that all inhabitants benefit from the advances of digital health.

> *‘Connectivity is expanding very fast, but not the digital services that can be employed for health. It’s pointless if a remote community health worker has a mobile phone but not the tool to, for example, receive health information or share data from their dispensary.’*
>
> Christoph Benn

Several panellists further argued that the dialogue around good health data governance, and promoting the key tenets outlined above, can serve as a catalyst for governments and their partners to invest in an equitable digital transformation of health systems, based on well-defined strategies.

The emphasis for governments and partners should be on expanding the digital services that can be used for health, not on expensive infrastructure investments to extend connectivity. The latter can be done by the private sector because there is significant commercial potential in connecting people. Access to mobile networks and the internet remains an issue for billions of people, but this digital divide is shrinking rapidly. However, where governments invest in digital technologies, some panellists found that all too often they prioritise the digitalisation of sectors that are thought to be more ‘productive’ than health, such as finance or transport.

The investments needed to transform the health sector digitally may be smaller and less spectacular than investments in other domains, but they can have even more impact. For example, smartphone-based applications can be relatively simple but enable remote health workers to send and receive information and to connect to digital diagnostic devices, transforming the service provided to the patient.

> *‘Necessary investments in the digital transformation are not as huge as people might think, but they still need to be made. This requires some political decision-making, the realisation of what is possible and then supporting that.’*
>
> Christoph Benn

What can Germany do to support partners' efforts in health data governance?

The Catalyst Dialogue participants unanimously agreed that Germany can play an important role in strengthening health data governance globally and in partner countries.

Champion a rights-based approach to digital health in the global arena

Several Catalyst Dialogue participants felt that Germany, as one of the largest funders of global health, could more proactively use its influential position in the relevant global governance fora such as WHO, or as board member of the major global health initiatives. Germany could push more strongly for a rights-based approach to the generation and use of digital health.

> *'Germany has contributed a lot to the work on the right to privacy and digital health within the UN and the work of the Human Rights Council. Playing a role in the global arena to push forward this rights-based approach to the use of digital health is really, really important.'*
>
> Alexandrine Pirlot de Corbion

Germany could also lend weight to demands that health data governance be open and inclusive, actively involving civil society and communities.
Moreover, the German government could promote a holistic approach to health data governance that considers a wide range of human rights aspects beyond privacy and data protection.

Support countries in strengthening health data governance

To help strengthen health data governance at the country level with practical measures as outlined previously, Germany is well placed to provide technical and financial assistance. The *Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH* (GIZ), with funding from and on behalf of Germany's Federal Ministry for Economic Cooperation and Development (BMZ), is recognised as a leading actor in supporting the digital transformation of health systems in partner countries.

Given Germany's experience in bilateral development cooperation, it can work with parliamentarians and civil society organisations in partner countries to provide information, stimulate debate and offer hands-on expertise to craft empowering normative frameworks for health data governance that are appropriate to their local contexts.

> *'Germany is acknowledged to have one of the most robust privacy laws in the world and the means to enforce it. Having this high standard can be a blueprint to help other countries come up with solutions that protect individuals, not only from commercial entities but also from the state intrusion.'*
>
> Christian Möhlen

Ensure good health data governance in German-supported projects

The ability and credibility of Germany to promote a rights-based and human-centred approach to digital health depends on its own determination to adhere to and insist on the highest standards.

Catalyst Dialogue participants recommended that Germany require organisations that operate with German funding to practice good health data governance. This should apply to German actors, such as GIZ, the KfW Development Bank and German consulting firms, as well as implementers in partner countries.

Implementing agencies should comply with the dual requirement of adopting a rights-based approach while adhering to the existing local and national legal frameworks on privacy and human rights.

> *“ The German government should put conditionalities on funding that it gives to German organisations operating in other countries. The conditionality could make sure that the organisation implements the Principles and abides by the data protection laws wherever they operate.’*
>
> Frances Baaba da-Costa Vroom

However, it would not be sufficient to make good health data governance practices an ex-ante requirement to qualify for German funding. Catalyst Dialogue participants called on Germany in its role as funding agency to conduct ‘human rights due diligence’ before, during and after implementation, monitoring the implementers’ compliance with the agreed requirements. The findings should inform programmatic and funding decisions, ensuring that (non-) compliance has consequences.

> *“ Germany as a funder should be undertaking human rights due diligence to make sure that the process is robust, open and inclusive, and for that due diligence to inform the programmes that are implemented and to be part of audits and evaluations happening later.’*
>
> Alexandrine Pirlot de Corbion

Germany has recently placed a new focus on developing a strategic vision and driving the digitalisation of its own health system. The Federal Ministry of Health released its domestic Digitalisation Strategy for Health and Care as recently as March 2023. The use of health data is one of the strategy’s ‘central action fields’. It incorporates important elements of the Health Data Governance Principles without referring to them explicitly.

The current momentum in AI and health research, and the buzz generated around ChatGPT, the AI-powered chat bot, have demonstrated the breathtaking pace of innovation that will inevitably transform digital health – with or without globally accepted rules. Now would be an opportune time for Germany to help shape a common global approach to how we generate, share and use our health data before the global marketplace makes these decisions for us.

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