

# International COVID-19 Data Alliance

*Designing a strategy to deliver meaningful  
Community, Public and Patient Involvement and  
Engagement*

*Live Working Document*

**February 2020**



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## Foreword

The International COVID-19 Data Alliance (ICODA) was set up to harness the power of health data to help respond to the COVID-19 global pandemic. Building trust and demonstrating trustworthiness in every aspect of what we do is central to our ability to have an impact. This will require the active engagement and involvement of the people whose data we are seeking to harness and who will benefit from the contribution we are seeking to make. Involving patients and the public in research is not only the right thing to do but it also ensures the right research is done, and that it is done right.

We are determined to embed meaningful global patient and public engagement and involvement into our strategy, governance and operations. Our key challenge is to determine how to do this effectively for a global initiative which is also prioritising working with low- and middle- income countries (LMICs). We are at an early stage in our development and are guided by our commitment to learn from and work with leaders in our field; taking a collaborative approach to developing our strategy is the right way forward to helping us achieve our aims. This report sets out the steps we have taken to do so, and our initial findings.

We would like to thank Bella Starling whose insights before, during and after the workshop as well as her masterful chairing of the virtual workshop were invaluable. We remain indebted to the patient, public and community involvement and engagement experts (see Annex A) who provided not only their time, but also invaluable insights to help meet our objectives.

**Julia Levy**

**Executive Director, International COVID-19 Data Alliance (ICODA)**

## 1. Executive Summary

The [International COVID-19 Data Alliance \(ICODA\)](#) is uniting partners to harness the power of health data to respond to the COVID-19 global pandemic. Our aim is to build and demonstrate a trustworthy approach to overcome the challenges of accessing data from around the world.

We can only build and sustain a trustworthy ecosystem for access to data if our work is informed by, and has the confidence of communities, the public, and patients. ICODEA is therefore determined to embed meaningful global involvement and engagement across our programme of work. The challenge is how to do this effectively for a global initiative, recognising the different approaches taken in different parts of the world as well as the differences in language used to describe ‘involvement and engagement’ approaches. For example, in the UK, the focus is increasingly on patient and public involvement, whereas in Kenya the emphasis is on community engagement. We have used the overarching phrase ‘working with patients, the public and communities’ and ‘Community Engagement and Patient and Public Involvement’ throughout this report to emphasise our desire to be as inclusive as possible whilst using existing terminology to avoid adding unnecessary jargon – see BOX 1 (*page 8*) for full list of definitions used. However, we want to be led by the community and are open to all suggestions on phrasing.

In order to help develop our approach, we have sought input from organisations across the world who are actively involved in engagement and involvement initiatives as well as members of the public and patient communities. This has been central to our way of working as we aim to take a collaborative approach to developing our strategy.

**a. Insights from survey and workshop**

Our first step was to circulate a short survey to groups engaged in Community Engagement and Patient and Public Involvement in the Global North and Global South. This was followed by a workshop in November 2020 with a range of international expert groups and patient and public representatives to define the key strategic, governance and operational considerations for ICODA to take into account as we develop our strategy.

Real-world usefulness, co-creation and transparency remaining fundamental to ensuring meaningful engagement were key themes that came out of the survey. It was also suggested that ICODA should work closely with groups disproportionately impacted by the pandemic and those from a low socioeconomic status. Workshop discussions took this further where participants discussed how ICODA could complement existing initiatives and explored ways to ensure transparency – see Sections 4 and 5 (page 12-22) of this report for a more in-depth overview of the findings from these discussions.

**b. Our proposed strategy**

Based on the insights we heard through these discussions, we have developed an initial strategy to embed our approach to working with patients, the public and communities in our governance and operations. This is based around four key recommendations:

- i. Embed public and patient voices in our governance
- ii. Work in partnership with expert groups in Community Engagement and Patient and Public Involvement
- iii. Ensure transparency throughout our work, emphasising inclusivity and accessibility, to continually build public trust
- iv. Focus on involvement and engagement for Driver Projects (exemplar research studies)

Section 5 (page 20) provides further detail about each of these recommendations. This is the start of our journey, and we will continue to collaborate with experts in the field to ensure that the community, patient and public voice is embedded in everything we do. This report describes the steps we will take to progress each of these elements during 2021.

## 2. Introduction

ICODA is an international collaboration of leading life science, philanthropic and research organisations uniting to respond to the COVID-19 global pandemic. Our mission is to build a trustworthy international partnership with a long-lasting and sustainable data analysis infrastructure to support a rapid response to the current COVID-19 pandemic that would also enable a more rapid response to future pandemics around the world.

We have created a powerful platform to bring together data from health research in a secure way and have made it accessible to scientists and researchers globally. We are particularly

focused on creating a resource that scientists from low- and middle-income countries can influence to lead their own projects and gain insight on COVID-19.

Convened by [Health Data Research UK \(HDR UK\)](#) – the national institute for health data in the UK – the founding members of ICODA bring together data assets, expertise and funding. ICODA has been funded by the [COVID-19 Therapeutics Accelerator](#), a large-scale initiative initiated by the Bill & Melinda Gates Foundation, Wellcome, Mastercard and other donors, with additional support from Minderoo Foundation, to accelerate the development of, and access to, therapies for COVID-19.

With increasing research around COVID-19, it is vital that the patient, public and community perspective be incorporated in the pandemic response, including at key decision-making stages. This is particularly important when health data is used, which can be both confidential and sensitive, in order to build, enhance and demonstrate trustworthiness. We recognise the ethical imperative to involve patients, communities and the public in research that is carried out in their name. We are committed to ensuring their involvement in our work, and they form an essential part of our collaboration.

This report sets out the steps ICODA is taking to ensure patients, the public and communities are **partners** in our efforts and involved in a process of co-creation to develop a meaningful global Community Engagement and Patient and Public Involvement strategy.

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*“Personally, I’m absolutely committed to Public and Patient Engagement and co-design as we define our response to the pandemic. In fact, Community Engagement and Patient and Involvement is not only essential in our quest to earn trust, it actually leads to better research and it has increased benefits for patients and citizens globally.”*

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Andrew Morris, HDR UK

a. **Context**

**Box 1: Definitions**

We recognise that a number of different terms are used for engaging with the public, patients and non-researchers, including: public engagement, community engagement, public outreach, public and patient involvement, and participation. These are often defined differently by different organisations, can come in many forms, and have a different emphasis in different parts of the world. We have therefore thought carefully about which phrase to use to enhance inclusivity.

**Community Engagement:** An umbrella term used to describe a wide variety of approaches which vary in practice from tokenistic forms of inclusion in health research decision-making, to de-centred participatory planning, knowledge co-production and resource development<sup>1</sup>

**Public and Patient Involvement:** Public involvement in research is defined as research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them.<sup>2</sup>

We recognise that these are not the same thing, although they have similar intention – to ensure that people feel informed, engaged and consulted – and whilst all are distinctive in its own right, there are overlaps. Throughout this report we have used a combined phrase of **working with communities, patients and the public** as well as **Community Engagement and Patient and Public Involvement**, to reflect that we want our activities to be relevant to those in all regions of the world and avoid adding unnecessary jargon into a crowded landscape. We recognise this may not be an ideal phrase but want to ensure that we are as inclusive as possible and understand that terminology can be important.

We recognise that terminology evolves and we will ensure to revisit this alongside our Partners and Advisors as the Community Engagement and Patient and Public Involvement strategy is developed and implemented to ensure it is fit for purpose. In the meantime, we welcome alternative suggestions.

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<sup>1</sup> <https://www.nihr.ac.uk/documents/researchers/manage-your-funding/NIHR-Community-Engagement-Involvement-Resource-Guide-2019.pdf>

<sup>2</sup> <https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/>



The value of involving patients, the public and communities as partners in health research is widely accepted<sup>3</sup>. The moral and ethical case for working with patients, the public and communities has long been established<sup>4</sup> and there is growing evidence that co-producing research delivers a considerable 'return on investment'. There are also numerous examples of good practice, including those captured in [Cochrane's ACTIVE research](#) as well as journals such as [Research Involvement and Engagement](#). However, as Tessa Richards, senior editor of the British Medical Journal pointed out, community engagement and patient and public involvement was largely absent at the start of the COVID-19 Pandemic<sup>5</sup>. In her article, she made a clear and compelling case for the critical need to address this gap, the argument being that lack of collaboration and sharing has a negative impact on the pandemic response.

The challenge is that community engagement and patient and public involvement is far from a global social movement. In some countries and cultures, there exist extensive barriers to working with patients, families, carers and civil society groups<sup>3</sup>. That is why, at the start of our journey, we knew we had to draw on the considerable experience, expertise and insights of leading community, patient and public involvement and engagement groups across the world to ensure our approach would help deliver our objectives.

ICODA is determined to embed meaningful global community engagement and patient and public involvement into our strategy, governance and operations. Our challenge is to determine how to do this effectively for a global initiative, while remaining inclusive and working in a way that embeds how different countries give voice to different communities, patients and members of the public. There will be learnings from international initiatives, such as the UN 2030 Agenda for Sustainable Development and the 17 Sustainable Development Goals who are working to implement their community engagement and patient and public involvement approaches<sup>6</sup>. This would include 'creating an enabling environment', 'ensuring no-one is left behind' and 'exploring interconnected agendas' to name a few<sup>6</sup>. Whilst there will still be elements on how to effectively embed the community, patient and public voice across ICODEA that are in the 'unknown', we are committed to working in a collaborative manner to find the best way forward.

## **b. Developing our approach**

With the response to COVID-19 accelerating at pace, how can we guarantee we involve and engage patients and the public in a meaningful way? How can we address the varying language, definitions, and goals of involvement between stakeholders, cultures and countries<sup>7</sup>?

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<sup>3</sup> Richards Tessa (2017). Tessa Richards: Patient and public involvement in research goes global.

<https://blogs.bmj.com/bmj/2017/11/30/tessa-richards-patient-and-public-involvement-in-research-goes-global/>

<sup>4</sup> Hoos A, Anderson J, Boutin M, Dewulf L, Geissler J, Johnston G, Joos A, Metcalf M, Regnante J, Sargeant I, Schneider RF, Todaro V, Tougas G. Partnering With Patients in the Development and Lifecycle of Medicines: A Call for Action. *Ther Innov Regul Sci*. 2015 Nov;49(6):929-939. doi: 10.1177/2168479015580384. PMID: 26539338; PMCID: PMC4616907.

<sup>5</sup> Richards, Tessa (2020) Patient and public involvement in covid-19 policy making, <https://www.bmj.com/content/370/bmj.m2575>

<sup>6</sup> <https://www.un.org/en/chronicle/article/participation-consultation-and-engagement-critical-elements-effective-implementation-2030-agenda>

<sup>7</sup> Boivin Antoine, Richards Tessa, Forsythe Laura, Grégoire Alexandre, L'Espérance Audrey, Abelson Julia et al. Evaluating patient and public involvement in research *BMJ* 2018; 363 :k5147

These questions particularly ring true for the work of ICODEA if we are to meaningfully embed the patient, public and community voice across our work.

It has been clear from the beginning, we need to have an informed approach, guided by the literature and the insights and processes of leading experts in community engagement and patient and public involvement from around the world – this includes members of lay and patient communities.

To gain wider insight and reach a broader group that suits individuals' preferences, a multifaceted approach was taken. A survey (see Section 4 (page 9), and Annex B (page 26)) was circulated to experts in community engagement and patient and public involvement across the world and also used to shape a subsequent Workshop with a range of patients, the public and professional experts in the field (see Section 5 (page 10), and Annex A (page 25)). This workshop was held virtually on Monday 9 November 2020 and Chaired by Dr Bella Starling, Wellcome Trust Engagement Fellow and Director of Vocal. We sought to capture best practice and address the questions that many organisations are facing around how to ensure meaningful lay involvement in an international initiative and continued this important discussion in a breakout group discussion at the [ICODA Forum](#) – a virtual inaugural event that took place on Thursday 19 November 2020.

Building on the insights from these discussions, we have developed a proposed strategy, described in Section 6 (page 23). We welcome comments on the suggested approach, which we see as the start of our journey to embed meaningful community engagement and patient and public involvement across all of ICODEA's activities.

### 3. Survey Findings

From the short survey (available in Annex B (page 26)) that was sent to groups engaged in community engagement and patient and public involvement in the Global North and Global South, a number of key themes emerged. Survey respondents told us that **real-world usefulness, co-creation and transparency** remain fundamental to ensuring meaningful engagement, while **transparency, involvement, understanding and access to IT** must be key considerations when engaging lay members around data access. In terms of the groups ICODEA should be engaging to inform its work, it was flagged that groups **disproportionately impacted by the pandemic** and from a **low socioeconomic status** should be prioritised.

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*“Something that resonates with the public is the concept of social determinants of health: in many countries COVID-19 affects the most vulnerable groups, so sharing data to improve understanding on how the pandemic affects different groups would be greatly welcome.”*

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Angela Coulter, Chair of HDR UK Public Advisory Board

Examples of the roles that some of the different organisations surveyed play include:

- “We provide a safe space for patient leaders to express our member's frustrations and aspirations.”
- “Our members and their members drive our work.”
- “...volunteers are involved throughout the process of producing evidence, from prioritisation to coproduction and dissemination and in the governance of the organisation.”
- “...we help the organisation achieve its goal of involving patients in all aspects of its work, essentially a strategic advisory role.”
- “...we work co-productively with the public in our work...”
- “...we work with researchers in all aspects of research.”

## 4. Workshop Report

### a. Strategic Considerations

#### a.i. Our vision needs to insist on public involvement and engagement, as well as transparency in all activities

All participants emphasised the need for Community Engagement and Public and Patient Involvement to be embedded in ICODA's overall vision. To do so, it will be critical for ICODA to understand the impact patients, the public and communities will have in the organisation, but also, and most importantly, what value ICODA can bring to them. It was suggested this is also important as many people might not understand the patient and public role. For this reason, working with communities, patients and the public should be seen as necessary and needed rather than as an optional activity.

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*"For patients and publics to be most empowered, it is important to listen to them before making a decision, rather than just asking them for their concern and then going off and making a decision ourselves."*

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Nicholas Brooks, Patient Focused Medicines Development (PFMD)

It was also agreed that ICODA required a Community Engagement and Patient and Public Involvement strategy to inform the governance and accountability of the overall initiative as well as ensuring that the community, patient and public voice is embedded in the individual Driver Projects. The strategy should also seek to produce tangible outputs, including examples that can be shared around innovation and learning. **[See Recommendation 1 and 4 in Section 5 (page 22) – Draft Strategy]**

#### a.ii. Our strategy must address the tension between delivering at pace and meaningful engagement and involvement

It was recognised that not only is ICODA operating in a pandemic situation, but it is also seeking to support the pandemic response. This brings with it issues of timeliness, especially when some models of community engagement and patient and public involvement rely on longer-term relationships. Participants stressed the necessity to respect the rights and needs of the public during a pandemic and highlighted that ICODA should ensure communities, patients and the public are placed centre-stage. It was also agreed that moving at pace should not come at the expense of public and patient needs.

This tension is highlighted by the Nuffield Council on Bioethics<sup>8</sup>, which recommends that organisations should undertake meaningful community engagement and patient and public involvement even within epidemic constraints. At the same time, it was also

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<sup>8</sup> Nuffield Council of Bioethics. COVID-19 and public involvement in research. <https://www.nuffieldbioethics.org/news/covid-19-and-public-involvement-in-research>

recognised that having a clear intent to work with and embed the community, patient and public voice into ICODA's work and governance and that starting with an initial set of actions which set the direction of travel were a strong starting point. This should then be combined with mechanisms to learn and develop the strategy over time.

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*"Although it is rarely possible to deliver perfectly against this from the start, it is important to show that you are striving to meet these ambitions at the outset, to set the tone."*

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Gary Hickey, International PPI Network

It was suggested that one way in which to accelerate community engagement and patient and public involvement in ICODA's work would be to work in partnership with local organisations to increase ICODA's capacity on the ground to work with communities, patients and the public. **[See Recommendation 2 in Section 5 (page 20) – Draft Strategy]**

**ICODA should support the development of a strategic framework for future pandemics, including for community engagement and patient and public involvement.**

COVID-19 has also uncovered gaps in health systems. For instance, in the UK it has revealed the lack of accessible data on patient conditions to effectively organise shielding (advice and guidance given to those considered clinically extremely vulnerable individuals to protect themselves by not leaving their homes and minimising all face-to-face contact). This poses a risk to patient rights in the face of a pandemic and highlights the need for legislative, policy and governance structures to be put in place to address future pandemics and ensure the voice of patients, the public and communities are heard and acted upon in key decisions. This would ensure countries can respond more quickly in the future, meet the needs of patients, the public and communities and is an important area of work that may arise as a priority for many organisations.

It was suggested that ICODA could play a role in supporting this ambition, particularly continuing ICODA's collaborative way of working, to be part of a coalition that builds on existing work and avoids duplication.

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*"COVID-19 has shown us that health systems don't know their patients well... we need to look at what legislative, policy and governance structures need to be in place to address future pandemics"*

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Kawaldip Sehmi, International Alliance of Patients' Organizations

- a.iii **Partnerships should be set up with existing networks to address gaps in community engagement and patient and public involvement and avoid duplication**  
A key theme that emerged from the workshop focused on the value of strategic partnerships to achieve three goals:

- To support potential partner organisations by addressing recognised gaps around data as well as community engagement and patient and public involvement
- To help meet shared goals at a rapid pace by sharing resources and frameworks, working to align on key processes and outcomes when working with patients, the public and communities and organising joint communications
- To avoid duplication and unwarranted competition with other organisations

It was agreed that it is paramount for ICODA to partner with likeminded organisations. Examples of potential partner organisations discussed included regional WHO structures, key Non-Governmental Organisations (NGOs) and the Global Alliance for Vaccines and Immunisation (GAVI), whereby ICODA could play an important role in tapping into the motivations and concerns of these groups. **[See Recommendation 2 in Section 5 (page 20) – Draft Strategy]**

It was also suggested that an option could be that of partnering with organisations that disperse funding to local organisations on the ground. This can help build the field in different regions and allow people to be responsible with funds and respond to specific needs.

b. **Governance considerations**

Strong governance is critical to ICODA's vision and mission, and to build a trusted global partnership. ICODA's governance bodies are described in Box 2 as well as an outline of the ICODA Forum.

## BOX 2: ICODA's Governance Bodies

- **Alliance Forum** – Provides a venue to bring all of our partners together, giving an opportunity to share ideas and input into our development.
- **Board** – Representatives from our key partners and advisory committees inform our high-level strategy and provide advice to the Executive Leadership Team. We are currently in the process of establishing the Board.
- **Advisory Councils** – International experts provide high-level advice through our Scientific & Strategic Advisory Council (to identify opportunities to ensure we deliver scientific impact) and our Ethics Advisory Council (to help us build a trustworthy system)
- **Expert Groups** – Specialist advisers to help inform our day-to-day operational decisions. We currently have a Statistics Expert Group to review analysis approaches and are seeking advice about creating an expert group to help embed the voice of communities, patients and the public across everything we do. These bodies advise and guide the work of our Leadership Team.
- **Executive Leadership Team** – Supervises delivery of the Workbench and Alliance.

### b.i **Effective CPPIE requires meaningful representation at all levels**

It was recognised there are two main ways to embed community engagement and patient and public involvement in governance structures; by integrating patients and the public at Board-level and/or by setting up independent advisory steering groups. While the latter can guarantee independence, they are not always embedded across all aspects of governance. The key is to have meaningful representation at all levels. **[See recommendation 1 in Section 5 (page 20) – Draft Strategy]**

Several participants agreed that a combination of these approaches could ensure meaningful representation as well as full integration in all aspects of ICODA's governance. There was also discussion around the role of reference groups or panels which could hold us accountable for our work. It was stressed that the role and remit of these groups would have to be very clear from the outset and that a robust evaluation process needs to be in place to ensure the patient, public and community voice is embedded, acted upon and in an environment that enables community engagement and patient and public involvement impact.

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*“Often there is a Community Engagement or Patient and Public Involvement group somewhere within an organisation, so it is easy to think that side is covered. Instead, to really ensure it is covered, we need to make sure it has representation at a very high, senior level.”*

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Debbie Keatley, Health Data Research UK

Communities, patients and the public should also be involved in the process and requirements for funding and have the opportunity to share their views on the robustness of project proposals. For example, the European Lung Foundation requires that applicants state how patients will be involved when applying for funding. **[See Recommendation 4 in Section 5 (page 20) – Draft Strategy]**

**b.ii Principles for engagement and involvement**

The group discussed how governance should ensure community engagement and patient and public involvement to provide input into research. It was suggested that ICODA should have shared principles for engagement and involvement and a plan for coordination. In terms of developing and defining these principles, there should not be a requirement for anything new as there are a number of existing principles in this space, including, but not limited to the:

- [UNICEF minimum quality standards and indicators in community engagement](#)
- [UN Participation and Accountability Goal \(Goal 16\) of the 2030 Agenda for Sustainable Development](#)
- [NIHR standards for public involvement](#)

**b.iii Operational considerations**

Discussion around ICODA's operational approach to embedding community engagement and patient and public involvement centred on the need to identify and reach the right patients, public and communities, with a particular focus on how best to engage seldom-heard groups.

**b.iv Identifying communities, patients and the public to engage**

Great emphasis was put on the need to identify the regions from which ICODA will be seeking community engagement and patient and public involvement to start a meaningful dialogue. However, it was also recognised that when starting out, an organization might begin by reaching out to existing contacts. However, once initial outreach has been established, diversity and inclusion must be prioritised. **[See Recommendations 2 and 4 in Section 5 (page 20) – Draft Strategy]**

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*“A co-creation process is key, depending on the geographical scope. We need to map the key partners and stakeholders comprehensively, bring them into this dialogue, and that is how you are going to ensure patient and public engagement.”*

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Claudious Chikozho, African Population and Health Research Center (APHRC)



**b.v Reaching key patients, the public and communities**

To meaningfully engage across different geographies, it was agreed that online channels may be the optimal approach. It was noted that COVID-19 has democratised the digital ecosystem, and generally made people more skilled at using it. However, there are caveats to this as **digital exclusion** is an issue, particularly for seldom-heard groups. Again, whilst this was recognised, a pragmatic approach to getting started with engagement and involvement was acknowledged.

Geographic representation from all relevant communities, such as paediatric, maternal, groups representing the elderly, and importantly mental health, must also be prioritized.

It was agreed that having in-country knowledge can help to identify the best approach to working with communities, patients and the public. Once frameworks have been established, the recommendation is that we engage with existing local groups. A question was raised about why existing groups should want to engage with us and how to make that a valuable experience on both sides.

**b.vi Transparency in all operations**

Ensuring transparency was discussed as a key objective and defined as demonstrating that ‘everything is open’. It was agreed that clarity around funders and funding was crucial. Determining how and where ICODA makes documents public was also a key consideration. Rather than lengthy meeting minutes, brief notes focused on key messages from the discussion should be prepared. Publishing background papers was also considered useful. Another consideration was the need to identify the best means to engage in a transparent manner, such as short emails, newsletters and the ICODA website. **[See Recommendation 3 in Section 5 (page 20) – Draft Strategy]**

Building trust amongst communities, patients and the public where mainstream government is not widely trusted is of utmost importance. It was noted that it takes time, energy and investment to build trust, which should be factored into ICODA’s operations.

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*“Trustworthiness is essential, especially when working with people that struggle to trust mainstream government, it takes time to build trust, but it can be built from working with existing and trusted organisations”*

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Debbie Keatley, Health Data Research UK

**b.vii Communications**

Closely linked to transparency is communications. It is recognised by all participants that in order to achieve full transparency, solid strategic communication is essential. Therefore, a key community engagement and patient and public involvement activity will be to co-produce a communications strategy and ensure key messages are developed with the guidance of patients, the public and communities as well as the methods we use to communicate.

Additionally, the importance of patient testimonies was emphasised, in that they help us communicate impact in tangible ways – however, it is vital this is done in a sensitive manner that does not take advantage of patient stories. Patient testimonies are of the utmost importance as they can help us understand and focus on what needs to be researched, and the potential impact of our work.

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*“I decided I would engage on social media and be a patient’s voice in a research project looking at potential treatments. You see, I remembered all the people in hospital who didn’t make it out of there to tell their story, and for me that became a great motivator, to speak for myself and on their behalf. I felt I had a duty. I noticed everyone was turning to me asking me what it was like, including doctors. I went to see my GP and he was asking me all these questions about what I had, how I felt, how I was diagnosed, how I was treated.”*

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Helen Parks, European Lung Foundation, Belfast

It is also recognised that communications and engagement need to reflect the international scope of the Alliance, prioritising those groups that have been disproportionately affected by the pandemic. This also has an impact on the choice of communication channels. For example, online channels offer a broad reach but risk excluding those who do not have access to digital media. **[See Recommendation 3 in Section 5 (page 20) – Draft Strategy]**

**b.viii Driver Project Case Study: The International Perinatal Outcomes in the Pandemic (iPOP) Study**

One of ICODA’s initial Driver Projects is the **International Perinatal Outcomes in the Pandemic (iPOP) Study**. iPOP researchers have been working with parent and patient representatives across different geographies to ensure the study’s methodologies and outcomes are relevant.

***What does iPOP seek to achieve?***

Preterm birth (PTB) is the leading cause of infant death worldwide. Whilst some insights into what causes PTB exist, the exact drivers remain largely unknown. During the early COVID-19 lockdowns, dramatic reductions in PTB (up to 90% in Denmark) and very low birth weight (70% Ireland) were observed – although data from Nepal showed a very different trend with reported increases in stillbirth. The potential drivers of PTB impacted by lockdown strategies include changing stress levels, a decline in maternity care, changes in nutrition, a decrease in air pollution, or increased hygiene.

The iPOP study has brought together over 100 researchers in more than 40 countries to understand the impact lockdown has had on pre-term births, the international trends and what is driving the changes. This includes:

- obstetricians (specialist doctors that focus on pregnancy, childbirth and the period after birth)

- neonatologists (specialist doctors who focus on the care of newborn infants, particularly those who are ill or premature newborns)
- epidemiologists (those who study outbreaks and causes of diseases and the effects on different communities)
- public health researchers
- environmental scientists
- policymakers

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*“We were there from beginning. We tried to inform our community about what is going on, why it’s important, in lay language”*

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Livia Nagy, iPOP parent representative, Hungary

#### **How is the patient and parent voice embedded in iPOP?**

It was critical to embed the parent and patient voice at the outset of the study. Indeed, patient groups and parents who have experienced pre-term birth were involved in the first meeting, where agreement was reached on the overall focus of the study. Since then, structures for formal Patient and Public Involvement and Community Engagement have been developed, from representation at all key meetings to the creation of a formal knowledge user and patient involvement group. This feeds directly into the leadership core. This group identifies and shapes the most important outcomes for parents and patients; and what is important to consider for patient engagement. The three main patient groups working with iPOP are the Canadian Premature Babies Foundation, Melletted a helyem Egyesület (Hungarian Association for Premature Birth Care), and Healthy Newborn Network, Irish Neonatal Health Alliance (INHA).

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*“Community engagement and patient and public involvement is well developed in certain countries like the UK, but it is newer in other parts of the world. We have great leaders in our Parent and Patient groups so we are looking forward to building on these foundations to inform our work”*

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Dr Merilee Brockway PhD, co-lead on the iPOP study

Together, we will leverage the most disruptive and widespread ‘natural experiment’ of our lifetime (the COVID-19 pandemic) to make rapid discoveries about PTB. Whether the pandemic is worsening or unexpectedly improving newborn health outcomes, our research will provide critical new information to shape prenatal care strategies throughout (and well beyond) the pandemic.

## 5. Draft Strategy

The survey, workshop and Forum breakout session gave a clear message: ICODA should ensure that patients, the public and communities are placed centre-stage, even within the constraints of a pandemic. Community Engagement and Patient and Public Involvement should therefore be seen as essential.

Building on the insights from the discussions to date, the following draft strategy has been developed. This is a **live working document** and the beginning of a collaborative and inclusive journey, with the ambition to embed and work with communities, patient and the public in a meaningful way across all of ICODA's activities.

### Recommendation 1: Embed community, patient and public voices in our governance

There was a strong message from the Workshop, that community engagement and patient and public involvement should be embedded throughout ICODA's governance, with meaningful representation at all levels.

- We will establish a dedicated **Public and Patient Advisors Expert Group** (*name to be determined by group once recruited*), with lay members from around the world to advise and influence from the community, patient and public perspective, ensuring recruitment is carried out in an inclusive manner.
- We will include representation from this Group in other parts of ICODA's governance, including having the Chair of the Expert Group become a full member of the Ethics Advisory Council.
- Other areas of ICODA's governance will ensure they are informed by the community, patient and public voice, but we will use a multi-faceted approach to maximise impact e.g., through the use of regular reports from the Public and Patient Advisors Expert Group and open meetings. These approaches are yet to be defined and we will seek the advice of expert groups in community engagement and patient and public involvement (our Strategic Partners) as well as the Public and Patient Advisors Expert Group once recruited.

These structures will be regularly evaluated to ensure their views, insights and perspectives are integrated and influencing the work of ICODA. As our structures evolve we will ensure the community, patient and public voice in governance is reviewed and ensure they are fully represented in decision-making processes. For example, if we establish an Independent Review Panel, we will ensure there is lay representation as part of the membership.

The Public and Patient Advisors Expert Group will have a number of functions, including to:

- provide advice on ICODA's day-to-day activities and operations
- advise and propose potential new opportunity areas that they believe are important for ICODA to consider
- highlight any areas of work that may affect public trust and advise on approaches to avoid any detrimental effects
- act as a sounding board, for example on a new policy or communications

- give hands-on guidance for new Driver Projects
- ensure accountability, including full transparency, on all areas of ICODA's work

This is not an exhaustive list - it will be further refined as we recruit to the Public and Patient Advisors Expert Group.

Our intention is to include public / patient representatives from all parts of the world on this group. To do this in a meaningful way, we need to:

- characterise the type of experience that is needed for this group (and why it is important),
- use this to determine and define appropriate roles in and outside of the Public and Patient Advisors Expert Group in more detail,
- agree whether members should be individuals or representatives of institutions, or a mix of the two.

Using clear criteria, we also need to explore ways to ensure the group is diverse and inclusive, and representative of every continent. Possible recruitment methods include:

- Inviting institutions with expertise in the area to nominate one or two individuals,
- Holding a targeted open call, promoted via initiatives with existing community engagement and patient and public involvement expertise,
- Building the group over time to include representatives from each Driver Project.

We recognise and acknowledge that this group can never be truly 'representative' of the Global North and Global South. Whilst ensuring a transparent process, inclusivity will be a key element that will help determine the approach. Outlining the key experiences that are needed for this group and why it is important will be a challenging but essential part of this process to try and address the 'representativeness' of the group. It will be important to have a mix of experiences and it will be the role of ICODA to ensure adequate support and training is provided. as well as ensuring we work closely with Strategic Partners and their lay and patient networks.

## **Recommendation 2: Work in partnership**

A key theme that was highlighted during the workshop was the importance of working in partnership, to build on existing learning, to help meet shared goals at rapid pace and to avoid duplication.

- We will invite expert groups in community engagement and patient and public involvement (e.g., MESH, Cochrane) to become Strategic Partners of ICODA, to provide ongoing input and guidance as we develop our strategy and embed the community, patient and public voice throughout our work.
- Partners with expertise in community engagement and patient and public involvement will be part of the Alliance Forum to provide ongoing advice and input.
- We will work with a network of partners to share ideas and best practice, and to broaden our engagement and involvement work by connecting with their lay and patient networks.

We will also put structures in place to work with our Strategic Partners and share learnings for community engagement and patients and public involvement outside of the Alliance Forum on a more regular basis. However, this will be further developed and refined as the expert groups are invited to become Strategic Partners.

The Workshop also highlighted the importance of demonstrating tangible outputs and learnings. If we are to contribute to global efforts to improve community engagement and patient and public involvement, it will be important to share best practice. We therefore intend to convene these partners regularly to facilitate the exchange of ideas and best practice. It will be important for us to learn from a network of existing bodies that are already actively engaging with patient and lay communities including, for example, the World Health Organisation.

We have been working with expert groups and individuals in community engagement and patient and public involvement to identify organisations that we should look to partner with moving forward. We want to be led by patients, the public and communities so **please do share any suggestions you may have using our [online form](#).**

### **Recommendation 3: Ensure transparency**

Demonstrating transparency is recognised to be an essential part of building trust, and the Workshop participants emphasised the importance of embedding meaningful transparency across all our activities.

- We will emphasise inclusivity and accessibility throughout all our communications, with a particular focus on explaining how data is used and how it is kept secure.

We are committed to transparency about the work of ICODA, our governance and oversight structures and outputs. This includes the activities and initiatives that fall under community engagement and patient and public involvement as well as the impact it has had on the strategy, governance and operations at ICODA and, where possible, wider society. Our communications for this will be key and we will work with lay members to ensure key messages that are important to patients, the public and communities are brought out and told in an engaging and accessible manner.

The main language we will use for the time being will remain English but we will ensure accessible language is used throughout. Acknowledging that not everyone has access to digital platforms, we will strive to be as inclusive as possible, taking into account the differences in communications across the globe and taking advice from community, patient and public groups on the ground.

### **Recommendation 4: Focus on involvement and engagement for Driver Projects**

From the outset, it was made clear the level of importance in demonstrating tangible examples and outputs and examples. We propose to do this through our Driver Projects – we use Driver Projects to guide and focus our work and are exemplar studies where ICODA is working in close partnership with data contributors to bring together datasets to address specific research

questions. Driver Projects aim to: use data and analysis tools to generate insights to priority questions to inform the prevention and treatment of COVID-19; and refine and improve systems, tools, and processes to help deliver the aims of ICODA.

- Driver Projects will provide an opportunity to ensure the community, patient and public voice is embedded in specific research projects from the outset, working closely with the data contributors.

We will do this in a number of ways, depending on the specific project, and will monitor the activity and the outcomes. The Public and Patient Advisors Expert Group will have a key role to play in advising on approach and we will work with lay members recruited specifically to each of the Driver Projects to help move it forward. The iPOP Driver Project Case Study (Section 5viii) gives an example from one of our first Driver Projects of how working with communities, patients and the public has been embedded and informs and shapes the direction of their work.

We have already committed to involving lay people in the review and assessment process for Grand Challenges and we will be transparent about the approach we take forward. Applicants to the Grand Challenge were invited to provide detail about any community engagement and patient and public involvement activity that they are planning and will form a solid basis to build on for the successful applicants/projects who will become our next set of Driver Projects.

## 6. Next Steps

The draft Community Engagement and Patient and Public Involvement Strategy is intended to describe the direction of travel, and to provide focus around an initial set of actions. We recognise this is the beginning of a journey, and we do not have all the answers. It is therefore crucial to ensure that mechanisms are in place to learn and iterate the Strategy over time, and to consult regularly with our partners and expert patient, public and community groups.

In order to progress the Strategy, the immediate actions are:

- Publish this report on the ICODA website, highlighting the live working strategy, to outline proposed commitment and approach to working with communities, patients and the public and gain insights from interested groups and populations.
  - Explore other ways in which to share learnings more broadly, with interested groups and communities, around the outputs from the survey and workshop as well as strategy development for an international initiative.
- Work up roles and remit for Public and Patient Advisors Expert Group, the experiences and profile of representatives needed (individuals only or also representatives of relevant institutions) and agree the best approach for recruiting members to this group.
- As an interim measure, continue to consult members of the Health Data Research UK and associated Patient and Public Networks to influence, guide and shape our activities and work.



- Ensure Community Engagement and Patient and Public Involvement is a criterion for assessing Grand Challenge applications and involve lay experts in the review process for Grand Challenge awards.
- Work with our Community Engagement and Patient and Public Involvement Strategic Partners and Public and Patient Advisors Expert Group to determine how best to measure the impact of working with communities, patients and the public across ICODEA's strategy, governance and operations.

**We're moving forward with bringing this strategy to life but it is a working document, as such we welcome input and feedback.**

**If you would like to share your views or provide advice on our approach please do complete our [online form](#) – we'd be very keen to hear from you!**



## Annex A: Workshop Participants

Bella Starling (workshop Chair)	Director Vocal, Wellcome Engagement Fellow
Angela Coulter	Chair of Health Data Research UK's Public Advisory Board
Annabel Grieve	Wellcome Trust/University of Cape Town
Clare Williams	European Lung Foundation
Claudious Chikozho	African Population and Health Research Center (APHRC)
Debbie Keatley	Health Data Research UK's Public Advisory Board Member
Doreen Tembo	National Institute for Health Research
Deborah Nyirenda	Malawi-Liverpool-Wellcome Trust Clinical Research Programme
Eleanor Perfetto	National Health Council (NHC)
Gary Hickey	International PPI Network
Georgia Bladon	Wellcome Trust/University of Cape Town
Helen Latchem	MESH Community Engagement Network
Kawaldip Sehmi	International Alliance of Patients' Organizations
Livia Nagy Bonnard	iPOP parent rep
Maria Fatima Garcia-Lorenzo	Philippine Alliance of Patient Organisations (PAPO)
Merilee Brockway	iPOP lead
Nicholas Brookes	Patient Focused Medicines Development (PFMD)
Patricia Kingori	Nuffield Department of Population Health
Richard Morley	Cochrane Consumer Network (CCN)



## Annex B: Survey Questions

Survey questions hosted on SurveyMonkey between 20 October 2020 and 11 November 2020, and distributed to a range of CPPIE organisations from the Global North and Global South:

1. What is the principal goal of your organisation?
2. What are your specific considerations of working collaboratively and/or in partnership with:
  - a. Patients
  - b. Members of the public
  - c. Your country or region
  - d. Your area of focus
3. How are patients, members of the public and communities involved in your work?
4. Please can you share with us what you think is a good example of working collaboratively with patients, and/or members of the public, and/or communities, in relation to data sharing for research? Please do not hesitate to share more than one example, or related examples.
5. In your opinion, what are the top three things the Alliance should take into consideration when engaging with patients, member of the public and communities in relation to data sharing?
6. Which relevant patient, public or community groups do you think the Alliance should engage to inform its work?

Insights from the answers received to these questions are incorporated into the report.