

The value of open-source clinical science in pandemic response: lessons from ISARIC

ISARIC Clinical Characterisation Group

Correspondence to: James Lee
James.lee@ndm.ox.ac.uk

Clinical data for improving public health

The International Severe Acute Respiratory and emerging Infection Consortium (ISARIC) is a global federation of clinical research networks that work collaboratively to prevent illness and deaths from infectious disease outbreaks. In 2014, we proposed that effective and timely research during outbreaks of emerging infections would benefit from pre-prepared research tools, global collaboration, and research-ready clinical networks (1). After applying this research model to several outbreaks, and particularly the COVID-19 pandemic, we can now explore what has been achieved to date.

ISARIC launched the Clinical Characterisation Protocol (CCP), in collaboration with the World Health Organization (WHO) in 2012 (1). A key aim was to avoid delays in initiating research, such as those seen during the 2009-2010 influenza A(H1N1)pdm09 pandemic and other outbreaks (2). The CCP protocol and associated case report forms (CRFs) were the first steps towards global, harmonised clinical datasets to create frameworks for characterizing current and potential future emerging infectious diseases. These adaptable research tools were developed and shared early in the pandemic by ISARIC (3) to prepare the health community for outbreak research.

Uptake and application of the ISARIC-WHO Clinical Characterisation Protocol

After receiving approvals from the WHO Ethics Committee in 2013 (9RPC571 & RPC572, 25/04/2013), the CCP was implemented in a variety of settings (**Figure 2, see appendices**). This broad uptake of the CCP, and the development of tools to support its implementation in a variety of diseases and contexts, meant that ISARIC partners were primed for a rapid response when COVID-19 emerged and spread in 2020. Working with WHO, ISARIC used early reports from Wuhan, China, to inform the adaptation of the case record form (CRF). On 24 January 2020, when less than 1000 cases had been reported globally, the ISARIC-WHO COVID-19 CRF was launched and made available globally (3). ISARIC provided a data management platform, utilising Research Electronic Data Capture (REDCap®), to collect and store data for institutions that lacked available resources or necessary infrastructure. Rapid access to the CRFs enabled collection of critical data for early characterization of the disease in hospitalized patients, first in Wuhan (4), and then globally (5-8). Institutions that chose to use the CRF and database simultaneously collected data for local analyses, and also contributed data for aggregated international analyses. As the pandemic progressed and an increasing number of institutions contributed data, the research benefits of a large, aggregated datasets also increased. To disseminate this knowledge, ISARIC and international collaborators issued the

first online report analysing risk factors, symptoms, treatments and outcomes of COVID-19 patients in March 2020 (9).

As of July 2021, 1651 sites in 57 countries have contributed data from 516,689 individuals with COVID-19 (**Figure 1, see appendices**), which includes 272,759 individuals from Low- and middle-income countries*. These data have informed a publicly available, regularly updated, clinical data report (<https://isaric.org/research/covid-19-clinical-research-resources/evidence-reports/>), with the aim of accelerating a collective understanding of COVID-19 globally. The data series have been published frequently on a preprint server (medrxiv.org), to help inform the development of policies and clinical management guidelines. Data continue to be collated and the latest aggregated report published in July 2021 (10) included eligible data from 516,689 cases. Through the collaborative platform, analyses are underway for over 20 studies.

* as defined by The Organisation for Economic Co-operation and Development (OECD)

Lessons learnt

This approach has enabled global collaborators to produce highly relevant outputs during a novel pandemic. Research preparedness helped avoid or minimise well known bottlenecks including protocol development, database set-up, contractual agreements, funding applications, ethics and regulatory approvals. Additionally, the open-access research tools enabled the standardised collection of high-quality data, for ease of aggregation and harmonisation. Bringing together a global community in a common data platform fosters a sense of solidarity and community, which is valued by collaborators and contributors (**Figure 3, see appendices**).

Coordinating research efforts during an evolving pandemic, across more than 1,600 institutions, is a significant undertaking and requires efficient systems to track and acknowledge contributors. Promoting local ownership of data and research strategy requires support to institutions with varying resource levels. The burden of data collection on healthcare workers, already facing considerable pressures, must be balanced with efficient systems to deliver high-calibre science that will inform and improve patient care. By supporting research groups with tools that are standardised but flexible, ISARIC has delivered an adaptive, observational infrastructure that enables the generation, collection, analysis, and dissemination of important knowledge during a pandemic. It highlights the fundamental importance of investment in research preparedness by healthcare systems, funders, and government organisations. Our COVID-19 experience has shown that a global collaborative approach, based on research-readiness in a peer to peer network, is achievable and effective. If this approach can be developed and maintained for future epidemic and pandemic research responses, the benefits should be even greater.

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Appendix 1

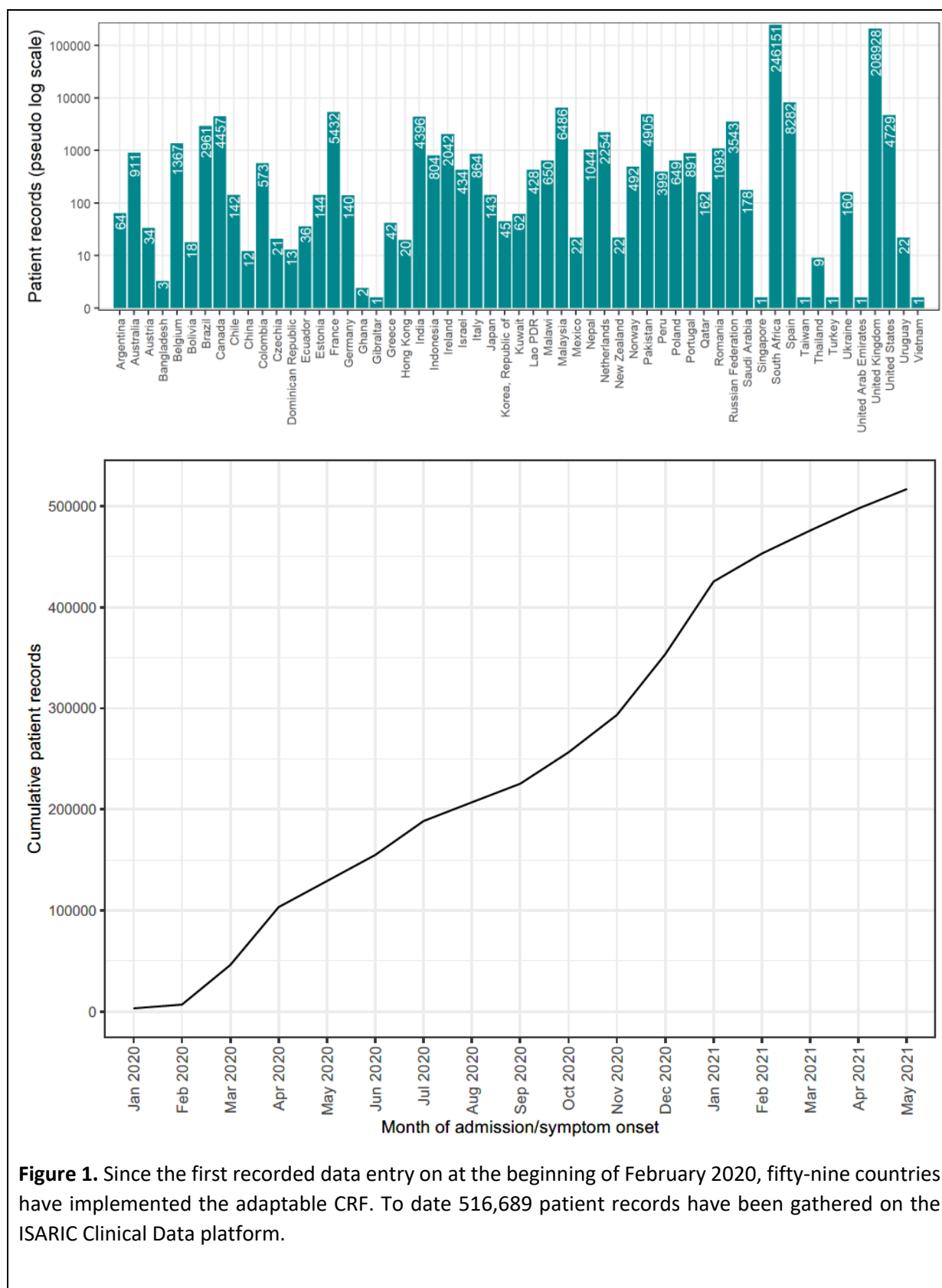


Figure 1. Since the first recorded data entry on at the beginning of February 2020, fifty-nine countries have implemented the adaptable CRF. To date 516,689 patient records have been gathered on the ISARIC Clinical Data platform.

PREPAREDNESS

Open-access, globally scalable framework

Clinical Characterisation Protocol & Case Report Forms

Implemented for MERS-CoV, Ebola, Zika, Monkey Pox, SARI

Steered by:



SARS-CoV-2 emerges,
spreads internationally

RESPONSE

Adaptation to SARS-CoV-2

ISARIC-WHO COVID-19 Clinical Characterisation Protocol & Case Report Forms

International dissemination & uptake. Data sharing framework.

Data shared from
hundreds of thousands
of patients
internationally

OUTPUTS

Globally-representative COVID-19 evidence

- Used in the first clinical description of COVID-19 patients (4)
- The largest global clinical research data platform
- ISARIC COVID-19 Clinical Data Reports (9,10)
- International network of sites contributing and analysing data (1,600 institutions)
- Tools and resources freely available from www.isaric.org

Figure 2. Preparedness activities have resulted in evidence and impact during infectious disease outbreaks.

Feedback from International Collaborators “This is tremendous work and unique to the field that despite all our challenges we are able to come together to learn from each other. Again, we appreciate the inclusion, transparency and we hope we can collaborate with the analysis that are under way.” USA

“It is an utmost pleasure collaborating with you and I hope that we will be able to meet as soon as pandemic is over.” Russia

“For us it is fundamental to collaborate with ISARIC Consortium and contribute quality data.” Spain

“On behalf of our institution, we would like to thank your great effort in coordinating this.” Malaysia

“The entire team deeply appreciates ISARIC for its constant support, even in times as difficult as these.” India

Figure 3. Selected quotes from global collaborators

ISARIC Clinical Characterisation Group

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Kestelyn, Evelyne; Khalid, Imrana; Khalid, Osama; Khalil, Antoine; Khan, Coralie; Khan, Irfan; Khanal, Sushil; Kherajani, Krish; Kho, Michelle E; Khoo, Denisa; Khoo, Ryan; Khoo, Saye; Khoso, Nasir; Kiat, Khor How; Kida, Yuri; Kiiza, Peter; Kildal, Anders Benjamin; Kim, Jae Burm; Kimmoun, Antoine; Kindgen-Milles, Detlef; Kitamura, Nobuya; Klenerman, Paul; Klont, Rob; Kloumann Bekken, Gry; Knight, Stephen; Kobbe, Robin; Kodippily, Chamira; Kohns Vasconcelos, Malte; Koirala, Sabin; Komatsu, Mamoru; Korten, Volkan; Kosgei, Caroline; Kpangon, Arsène; Krawczyk, Karolina; Krishnan, Vinothini; Kruglova, Oksana; Kumar, Deepali; Kumar, Ganesh; Kumar, Ashok; Kumar, Mukesh; Kumar Tirupakuzhi Vijayaraghavan, Bharath; Kumar Vecham, Pavan; Kurtzman, Ethan; Kusumastuti, Neurinda Permata; Kutsogiannis, Demetrios; Kutsyna, Galyna; Kyriakoulis, Konstantinos; Lachatre, Marie; Lacoste, Marie; Laffey, John G.; Lagrange, Marie; Laine, Fabrice; Lairez, Olivier; Lalueza Blanco, Antonio; Lambert, Marc; Lamontagne, François; Langelot-Richard, Marie; Langlois, Vincent; Lantang, Eka Yudha; Lanza, Marina; Laouénan, Cédric; Laribi, Samira; Lariviere, Delphine; Lasry, Stéphane; Lath, Sakshi; Latif, Naveed; Launay, Odile; Laureillard, Didier; Lavie-Badie, Yoan; Law, Andrew; Lawrence, Cassie; Le, Minh; Le Bihan, Clément; Le Bris, Cyril; Le Falher, Georges; Le Fevre, Lucie; Le Hingrat, Quentin; Le Maréchal, Marion; Le Mestre, Soizic; Le Moal, Gwenaël; Le Moing, Vincent; Le Nagard, Hervé; Le Turnier, Paul; Leal, Ema; Leal Santos, Marta; Lee, Biing Horng; Lee, Heng Gee; Lee, Su Hwan; Lee, James; Lee, Todd C.; Lee, Yi Lin; Leeming, Gary; Lefebvre, Bénédicte; Lefebvre, Laurent; Lefevre, Benjamin; LeGac, Sylvie; Lelievre, Jean-Daniel; Lellouche, François; Lemaignan, Adrien; Lemee, Véronique; Lemeur, Anthony; Lemmink, Gretchen; Lene, Ha Sha; León, Rafael; Leone, Marc; Leone, Michela; Lepiller, Quentin; Lescure, François-Xavier; Lesens, Olivier; Lesouhaitier, Mathieu; Levy, Bruno; Levy, Yves; Levy-Marchal, Claire; Lewandowska,

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P. Sanka Ruwan; Sriskandan, Shiranee; Stabler, Sarah; Staudinger, Thomas; Stecher, Stephanie-Susanne; Steinsvik,

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Appendix 3

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Allavena, C. declares personal fees from ViiVHealthcare, MSD, Janssen and Gilead, all outside the submitted work.

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Póvoas, D. declares consulting fees (for lectures and/or participation in advisory boards) from Roche and Viiv Healthcare; and travel/accommodation/meeting expenses from Abbvie, Gilead Sciences, Janssen Cilag, Merck Sharp & Dohme and ViiV Healthcare

Rewa, O. declares consulting fees from Baxter Inc.

Rossanese, A. declares consulting fees (for lectures and/or participation to advisory boards) from Emergent BioSolutions and Sanofi Pasteur, but all outside of the frame of the submitted work.

Săndulescu, O. has been an investigator in COVID-19 clinical trials by Algernon Pharmaceuticals, Atea Pharmaceuticals, Regeneron Pharmaceuticals, Diffusion Pharmaceuticals, and Celltrion, Inc., outside the scope of the submitted work.

Semple, M.G. reports grants from DHSC National Institute of Health Research UK, from the Medical Research Council UK, and from the Health Protection Research Unit in Emerging & Zoonotic Infections, University of Liverpool, supporting the conduct of the study; other interest in Integrum Scientific LLC, Greensboro, NC, USA, outside the submitted work.

Serpa Neto, A. declares personal lecture fees from Drager outside the submitted work.

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Streinu-Cercel, Adrian has been an investigator in COVID-19 clinical trials by Algernon Pharmaceuticals, Atea Pharmaceuticals, Regeneron Pharmaceuticals, Diffusion Pharmaceuticals, and Celltrion, Inc., outside the scope of the submitted work.

Streinu-Cercel, Anca has been an investigator in COVID-19 clinical trials by Algernon Pharmaceuticals, Atea Pharmaceuticals, Regeneron Pharmaceuticals, Diffusion Pharmaceuticals, and Celltrion, Inc., outside the scope of the submitted work.

Summers, C. reports that she has received fees for consultancy for Abbvie relating to COVID-19 therapeutics. She was also the UK Chief Investigator of a GlaxoSmithKline plc sponsored study of a therapy for COVID, and is a member of the UK COVID Therapeutic Advisory Panel (UK-CTAP). Outside the scope of this work, Dr Summers' institution receives research grants from the Wellcome Trust, UKRI/MRC, National Institute for Health Research (NIHR), GlaxoSmithKline and AstraZeneca to support research in her laboratory.

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Timsit, J.F. declares personal fees from Merck, Pfizer, Gilead, Beckton dickinson, Medimune, Bayer pharma, and reports research grants to his research unit from Pfizerpers, Merck, Thermofisher.

Troost, J. declares personal fees from General Electric and Procter and Gamble.

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Visseaux B. declares personal fees from BioMérieux, Qiagen and Gilead and research grants from Qiagen, all outside the submitted work.

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Guerguerian AM. Participated as site investigator for the Hospital For Sick Children, Toronto, Canada as a site through SPRINT-SARI Study via the Canadian Critical Care Trials Group sponsored in part by the Canadian Institutes of Health Research.