

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

ISARIC Clinical Characterisation Group

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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 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 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 REDCap®, to collect and store data for institutions that lacked appropriate 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, as well as contributing data for aggregated international analyses. As the pandemic progressed and an increasing number of institutions contributed data, the 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 2,100 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 under 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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Appendices

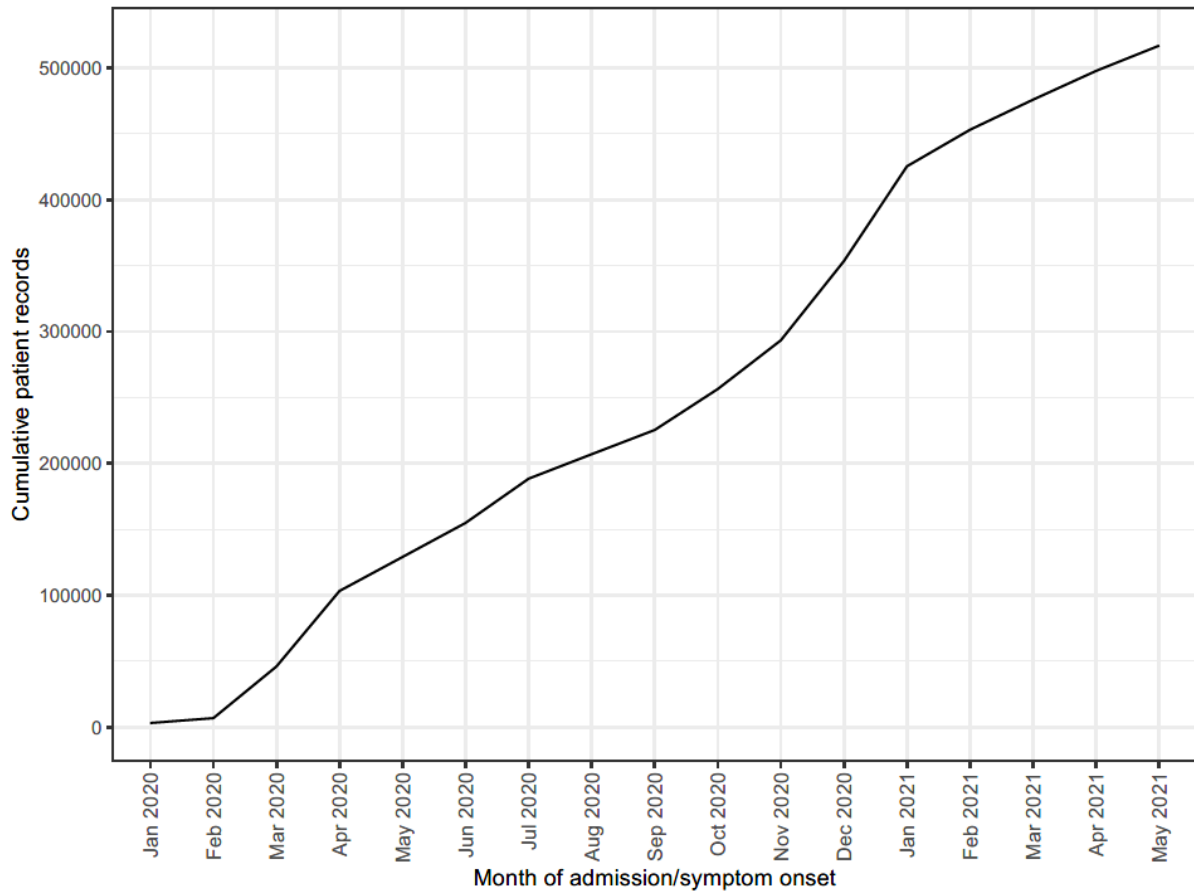
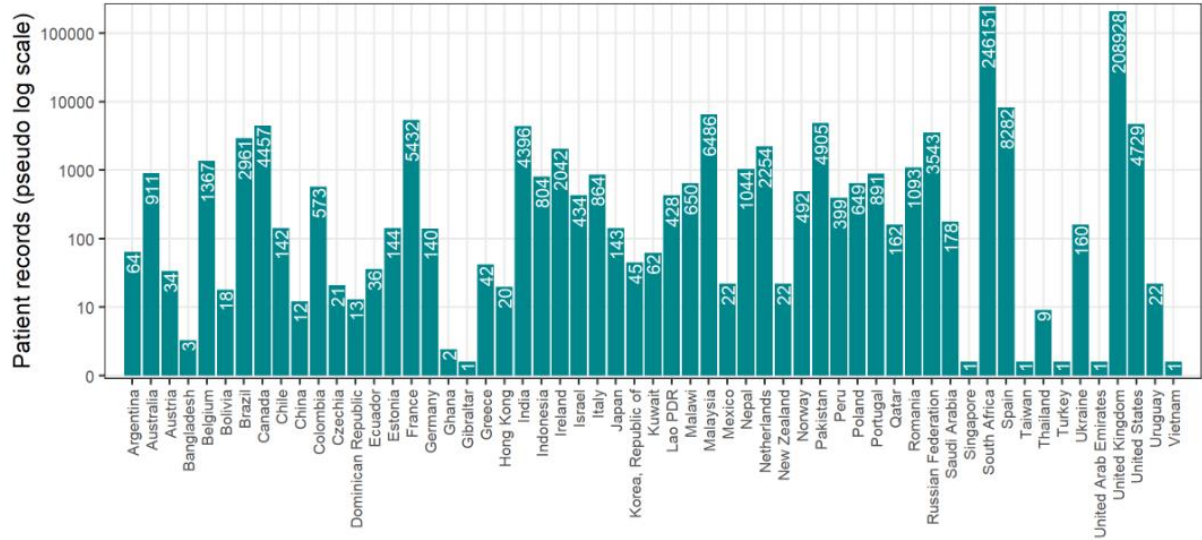


Figure 1. Since the first recorded data entry on at the beginning of February 2020, fifty-nine countries have implemented the adaptable CRF. To date 516,689 patient records have been gathered on the ISARIC Clinical Data platform.

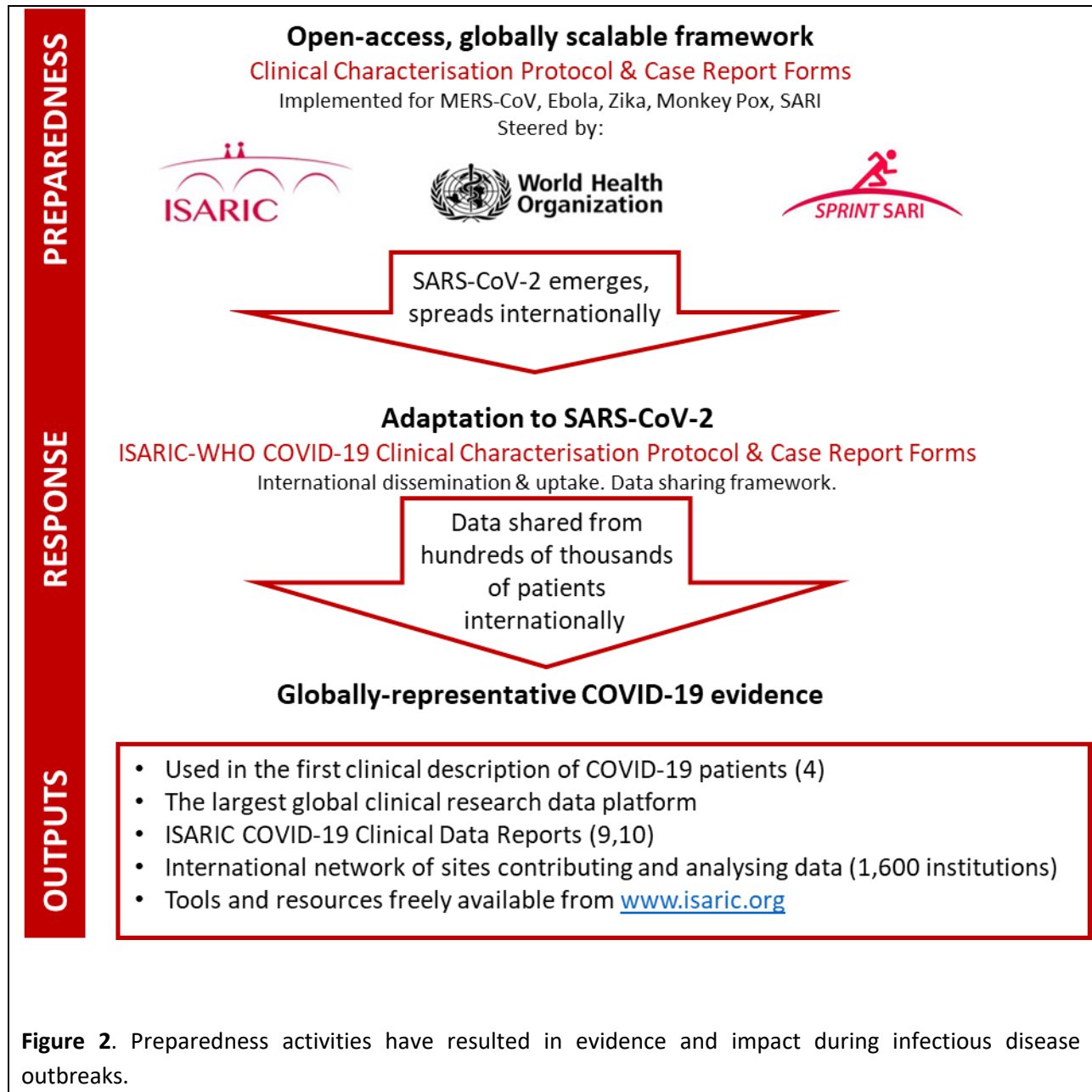


Figure 2. Preparedness activities have resulted in evidence and impact during infectious disease outbreaks.

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

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Conflict of Interest (Col) Declarations

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

Andréjak, C. declares personal fees for lecture from Astra Zeneca, outside the submitted work.

Cheng, M. declares grants from McGill Interdisciplinary Initiative in Infection and Immunity, grants from Canadian Institutes of Health Research, during the conduct of the study; personal fees from GEn1E Lifesciences (as a member of the scientific advisory board), personal fees from nplex biosciences (as a member of the scientific advisory board), outside the submitted work. He is the co-founder of Kanvas Biosciences and owns equity in the company. In addition, M. Cheng reports a patent Methods for detecting tissue damage, graft versus host disease, and infections using cell-free DNA profiling pending, and a patent Methods for assessing the severity and progression of SARS-CoV-2 infections using cell-free DNA pending.

Cholley, B. declares personal fees (for lectures and participation to advisory boards) from Edwards, Amomed, Nordic Pharma, and Orion Pharma.

Cruz-Bermúdez, J.L. declares personal fees from Elsevier for advice, outside the submitted work

Cummings, M. and O'Donnell, M. participated as investigators for clinical trials evaluating the efficacy and safety of remdesivir (sponsored by Gilead Sciences) and convalescent plasma (sponsored by Amazon) in hospitalized patients with COVID-19. Support for this work is paid to Columbia University.

Dalton, H. declares personal fees for medical director of Innovative ECMO Concepts and honorarium from Abiomed/BREETHE Oxi-1 and Instrumentation Labs.

Dyrhol-Riise, AM, declares grants from Gilead outside this work.

Deplanque, D. declares personal fees from Biocodex, Bristol-Myers Squibb and Pfizer (advisory boards)

Susanne Dudman has also received this grant no 312780 from the Norwegian Research Council

Durante-Mangoni, E. declares funding via his Institution from MSD, Pfizer, and personal fees or participation in advisory boards or participation to the speaker's bureau of Roche, Pfizer, MSD, Angelini, Correvio, Nordic Pharma, Bio-Merieux, Abbvie, Sanofi-Aventis, Medtronic, Tyrx and DiaSorin.

Gordon, AC. reports a Research Professorship from NIHR (RP-2015-06-18), and consulting fees from GlaxoSmithKline, Bristol Myers Squibb and 30 Respiratory paid to his institution outside of the submitted work

Grasselli, G. declares personal fees from Getinge, Biotest, Draeger Medical, Fisher & Paykel, MSD and unrestricted research grant from MSD and Fisher & Paykel, all outside the submitted work.

Ho, A. declares grant funding from Medical Research Council UK, Scottish Funding Council - Grand Challenges Research Fund, and the Wellcome Trust, outside this submitted work.

Holter, J. C. reports grants from Research Council of Norway grant no 312780, and from Vivaldi Invest A/S owned by Jon Stephenson von Tetzchner, during the conduct of the study.

Kimmoun, A. declares personal fees (payment for lectures) from Baxter, Aguetant, Aspen.

Kumar, D. declares grants and personal fees from Roche, GSK and Merck; and personal fees from Pfizer and Sanofi.

Kutsogiannis, D.J. declares personal fees for a lecture from Tabuk Pharmaceuticals and the Saudi Critical Care Society

Kutsyna, G. declares the study consulting fee for clinical trial ClinicalTrials.gov Identifier: NCT04762628

Laffey, J. reports that he has received fees for consultancy from GlaxoSmithKline and from Baxter Therapeutics for work outside the scope of this work.

Lairez, O. declares grant funding from Pfizer; conference fees from Amicus, GE Healthcare, Novartis, Sanofi-Genzyme, and Takeda-Shire; and consultancy fees from Alnylam, Amicus, Pfizer, Takeda-Shire.

Lee, J. reports grants from European Commission PREPARE grant agreement No 602525, European Commission RECOVER Grant Agreement No 101003589 and European Commission ECRAID-Plan Grant Agreement 825715 supporting the conduct, coordination and management of the work.

Lee, T.C. declares research salary support from les Fonds de recherche du Québec – Santé.

Lefèvre, B. declares travel/accommodation/meeting expenses from Mylan and Gilead, all outside the submitted work.

Lemaignen, A. declares personal fees (payment for lectures) from MSD and Gilead; and travel/accommodation/meeting expenses from Pfizer.

Lescure, F.X. declares personal fees (payment for lectures) from Gilead, MSD; and travel/accommodation/meeting expenses from Astellas, Eumedica, MSD.

Liu, K. reports personal fees from MERA and receives a salary from TXP Medical completely outside the submitted work.

Martin-Loeches I. declares consulting fees for Gilead outside of the submitted work.

Martín-Quiros, A. declares consulting fees for Gilead.

Mentré F, declares consulting fees from IPSEN, Servier and Da Volterra, and reports research grants to her group from Sanofi, Roche, Servier and Da Voleterra, all outside the submitted work.

Murthy, S declares receiving salary support from the Health Research Foundation and Innovative Medicines Canada Chair in Pandemic Preparedness Research.

Nichol, A. declares a grant from the Health Research Board of Ireland to support data collection in Ireland (CTN-2014-012).

Openshaw, P. has served on scientific advisory boards for Janssen/J&J, Oxford Immunotech Ltd, GSK, Nestle and Pfizer (fees to Imperial College). He is Imperial College lead investigator on EMINENT, a consortium funded by the MRC and GSK. He is a member of the RSV Consortium in Europe (RESCEU) and Inno4Vac, Innovative Medicines Initiatives (IMI) from the European Union.

Peltan, I.D. declares grant support from the National Institutes of Health and, outside the submitted work, grant support from Centers for Disease Control and Prevention, and Janssen and payments to his institution for trials by Regeneron and Asahi Kasei Pharma on which he served as an investigator.

Pesenti, A. declares personal fees from Maquet, Novalung/Xenios, Baxter, and Boehringer Ingelheim.

Poissy, J. declares personal fees from Gilead for lectures, outside the submitting work

Povoa, P. declares personal fees (for lectures and advisory boards) from MSD, Technophage, Sanofi, and Gilead.

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.

Shrapnel, S. participated as an investigator for an observational study analysing ICU patients with COVID-19 (for the Critical Care Consortium including ECMOCARD) funded by The Prince Charles Hospital Foundation during the conduct of this study. S. Shrapnel reports in kind support from the Australian Research Council Centre of Excellence for Engineered Quantum Systems (CE170100009).

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.

Tedder, R. reports grants from MRC/UKRI during the conduct of the study. In addition, R. Tedder has a patent United Kingdom Patent Application No. 2014047.1 "SARS-CoV-2 antibody detection assay" issued.

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.

Ullrich, R. reports grant funding to his institution from Apeptico, APEIRON, Biotest, Bayer, CCORE and Philips, as well as personal fees from Biotest. He holds European patent EP15189777.4 "Blood purification device" and equity in CCORE Technology GesmbH, a medical device research and development company.

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

West, E. reports grant funding from the Firland Foundation, the US CDC, and the Bill and Melinda Gates Foundation for studies of COVID-19, and grant funding from the US NIH for studies of other respiratory infections.

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 of Health Research.

