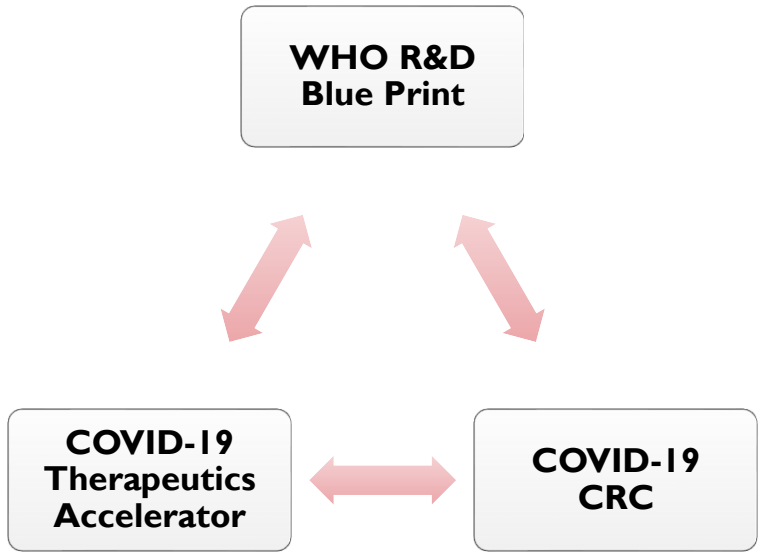
COVID19
CLINICAL RESEARCH COALITION

ACCELERATING CLINICAL RESEARCH TO MEET THE SPECIFIC NEEDS OF RESOURCE-LIMITED SETTINGS

- **Facilitate trials**
  - Rapid and joint protocol reviews by ethics committees and regulatory agencies
  - Approvals for the importation of study medications through agreed coordinated fast-track mechanisms
- **Network initiatives**
  - build on each others' strength and ensure effective and prompt scale up of research while addressing bottlenecks and jointly
- **Ensure standardized and rapidly shared data**
  - Simple standards collection of key endpoints
  - Sufficient for robust analysis of efficacy and safety data
- **Propose data governance**
  - Efficient, transparent, and swift data governance framework to share outcomes swiftly before publication

The work of the Coalition is guided by the WHO COVID-19 R&D Blueprint and the COVID-19 Therapeutics Accelerator



COVID-19 Clinical Research Coalition

FOCUS OF THE **COVID-19 CRC**

6 work packages:

- **Therapeutics** e.g. early stage disease, village-based treatment, severe illness
- **Preventive medicines** e.g. preventive treatment for health care workers (HCW), post exposure prevention
- **Vaccines**
- **Diagnostics** testing or validating diagnostic tools
- **Social Science** examining the social determinants of the disease e.g. behavioural studies, ethical issues
- **Epidemiology and modelling**

Key areas of accelerated collaboration

- **Ethics**
- **Data sharing**
- Pharmacometrics
- Accelerated registration strategies
- Supply and quality assurance….

Proactively support acceleration of trials proposed by members of the coalition,

such as, in the therapeutic area:

- **Therapeutics work package** – Early diagnosis and treatment – e.g., ANTICOV (Coordinator: DND*i*)
- **Preventive medicines and diagnosis work packages** – Prevention of Coronavirus Disease (COPCOV) in health care workers and high-risk groups (investigator: MORU)
- **Other protocols as they emerge from members consultations**

COVID-19 Clinical Research Coalition

SUPPORTING ACTIVITIES FOR **COVID19 CLINICAL RESEARCH COALITION**

1

- **Membership development:** emphasis on effective representation and leadership of LMICs
- **Virtual infrastructure development and management:** promote and facilitate dialogue between 200-500 experts via various working groups
- **Scientific support**: Accelerating development of networked COVID-19 clinical trials in resource-limited settings
  - key principles of standardization and data sharing, supply of trial drugs materials
- **Facilitation of members dialogue and co-creation**: ensure results-orientation, best practice, and dissemination of tools
- **External communications:** Ensure effective mobilisation, representation and dissemination

2

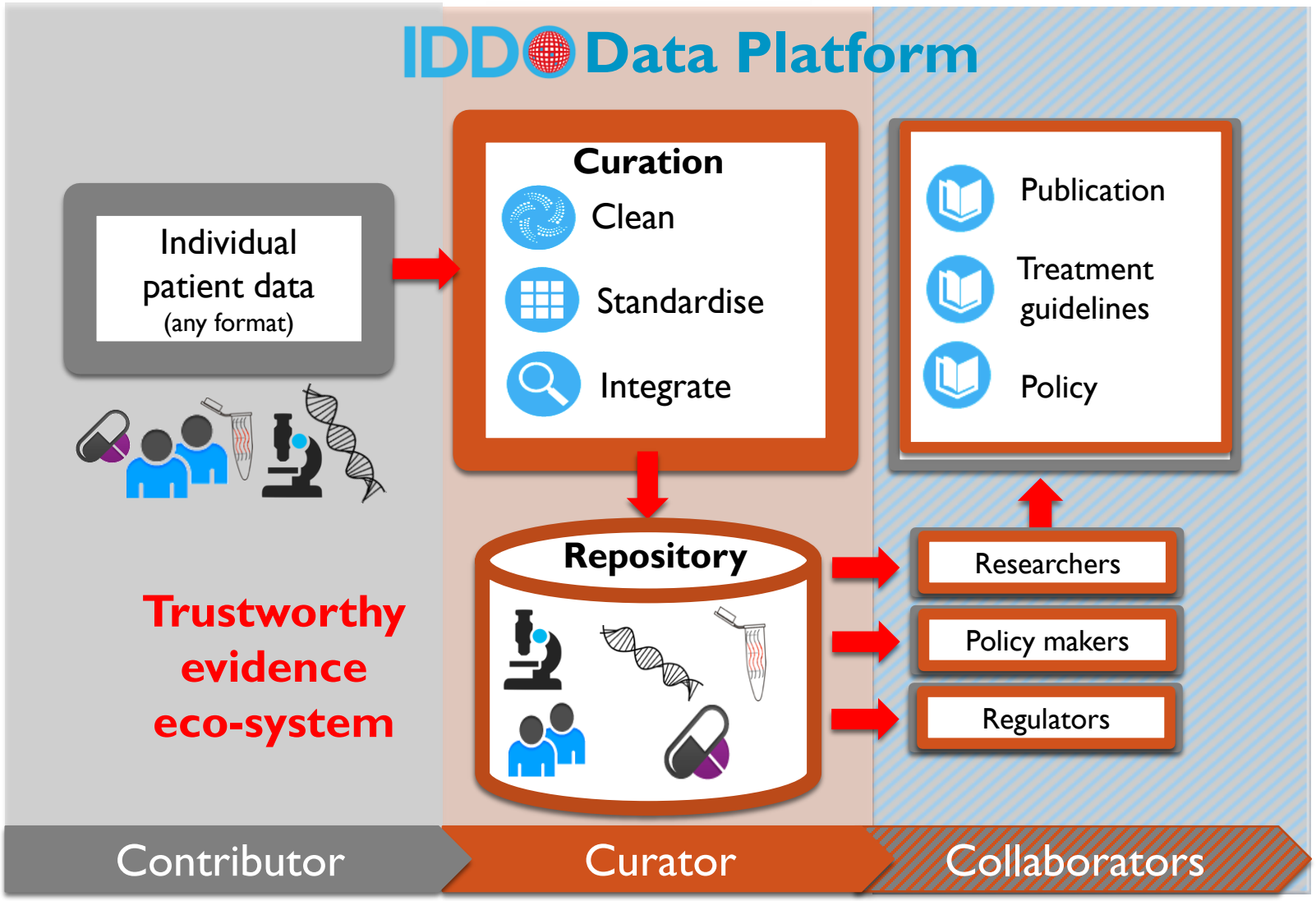
- **Develop a live COVID-19 systematic trial review and metadata capture:** extract, curate and incorporate new clinical trial registrations and relevant data as they become available
- **Global data sharing and standards:** Tools, systems, and support to facilitate standardized collection, aggregation, and analysis of clinical data
  - **Development of COVID-19 CDISC TAUG development and dissemination:** Support each trial under the coalition to develop a CDSIC-compatible CRF
  - **Medicine quality for COVID-19:** Mapping, monitoring and analysing medicine quality reports and supply during the COVID-19 pandemic response

COVID-19 Clinical Research Coalition

IDDO & ISARIC

Infectious Diseases Data Observatory (IDDO) & International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC)

IDDO
INFECTIOUS DISEASES DATA OBSERVATORY



https://www.iddo.org/

ISARIC

INTERNATIONAL SEVERE ACUTE RESPIRATORY AND EMERGING INFECTION CONSORTIUM

- Prevent illness and deaths from infectious disease outbreaks.
- Global federation of clinical research networks
- Coordinated, research response to outbreak-prone infectious diseases

Clinical Data collections – CRFs collection of standardised clinical data to improve patient care and inform the public health response.

Data Management and Hosting - a secure electronic data capture system

Clinical characterization protocol - standardised protocol that enables data and biological samples to be collected rapidly in a globally-harmonised manner.

https://isaric.tghn.org/

COVID Clinical Trials

1. Severe Disease – Treatment Trials
2. Hospitalised patients
3. Prophylaxis – Vaccine and drug
4. Post exposure prophylaxis – high risk groups

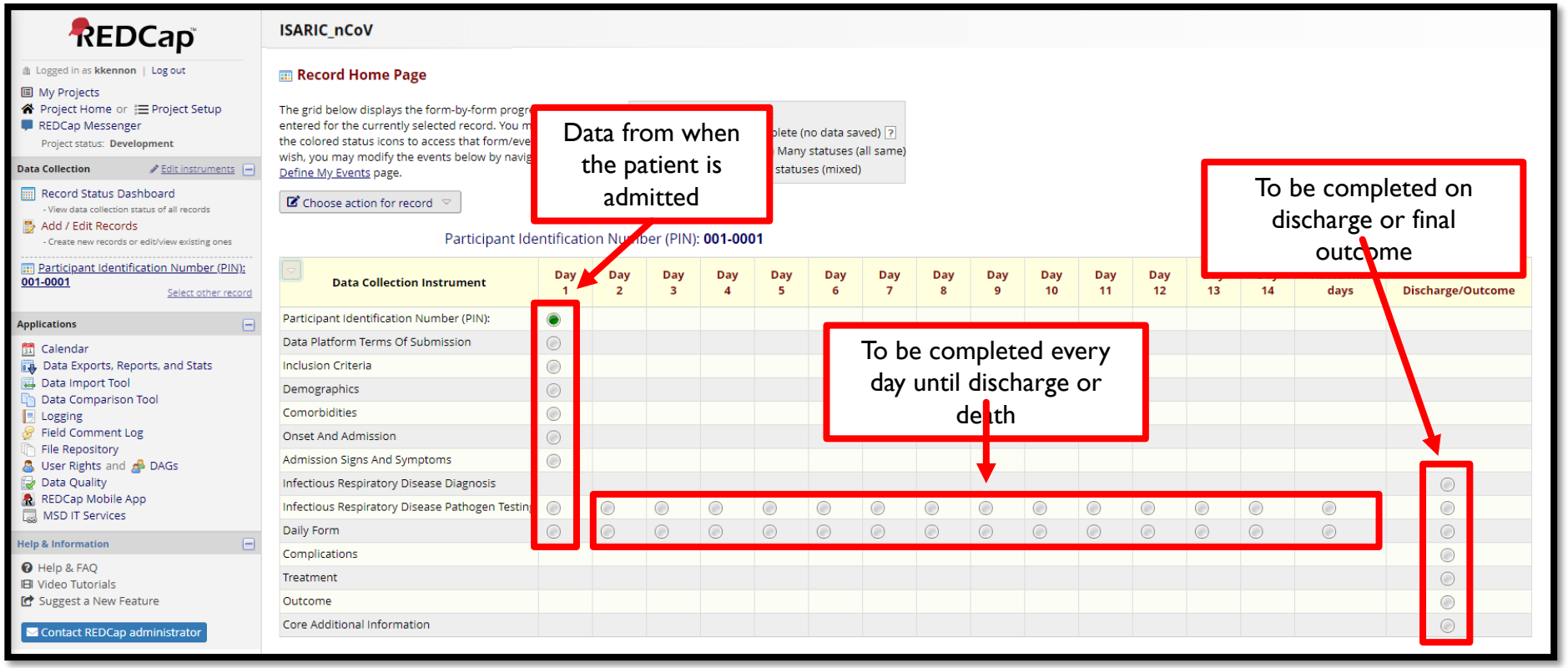
<u>Challenges:</u>
Urgency
Variable caseload – few to swamped
Overlap and competition
Heterogeneous dosing regimens
Singularly Underpowered

PROMOTE KEY RCTS

- Quality: design, RCT, prospective, ethical,
- Inclusive - Protocol sharing and multiple sites
- Committed to early data sharing and metanalyses
- Data management – CDISC standards

  - RECOVERY - https://www.recoverytrial.net/ (> 6000 patients)
  - ASCOT - https://clinicaltrials.gov/ct2/show/NCT04280705
  - PRINCIPLE - https://doi.org/10.1186/ISRCTN86534580
  - REMAPCAP - https://www.remapcap.org/background
  - SOLIDARITY - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

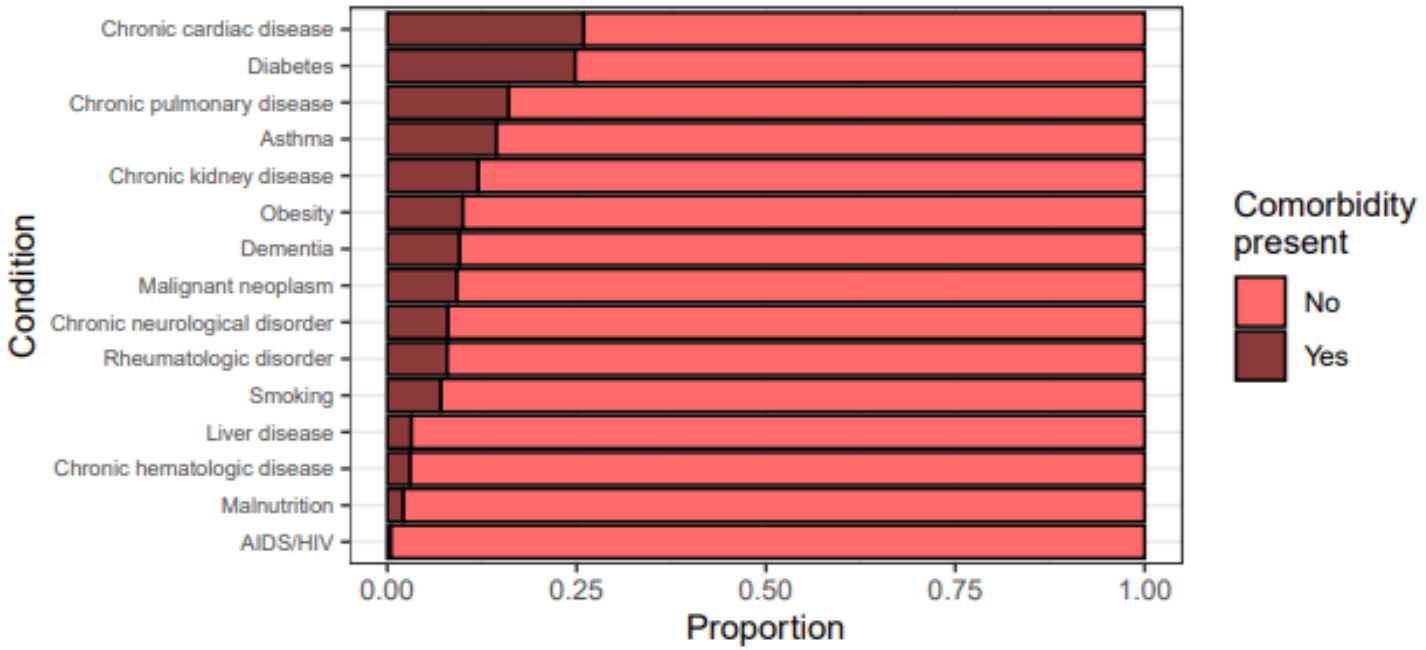
DATA ENTRY SCHEDULE



ISARIC

International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC)

8th April – 10,363 patients from 240 sites, 25 countries
Cohort data on 3316 - > 14 days follow-up
Automated reports



https://media.tghn.org/medialibrary/2020/04/ISARIC_Data_Platform_COVID-19_Report_8APR20.pdf

IDDO
INFECTIOUS DISEASES DATA OBSERVATORY

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https://www.iddo.org/