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Summary of the Jan 9 consultation- A Scientific Framework for Epidemic & Pandemic Preparedness

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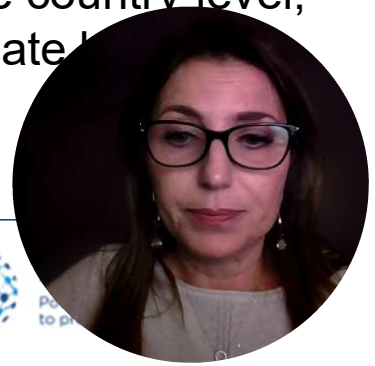
Objectives of January 9 Meeting

A scientific framework for epidemic and pandemic research preparedness

- To discuss the scientific opportunities and challenges for all viral and bacterial families, regardless of perceived pandemic potential
  - Define the scope of emerging virus threats through discovery
  - Discuss generalizable basic research that supports the development of vaccines for future threats
- To outline cross-cutting scientific actions that are needed, globally and at the country-level, to address development challenges including global collaboration to coordinate
translational research as part of pandemic preparedness



A SCIENTIFIC APPROACH TO PANDEMIC PREPAREDNESS- BARNEY GRAHAM

- Emerging infections are a large but finite problem
  - 150 viruses from 26 families recognized as human pathogens with potential for person-to-person spread
- Pandemic Preparedness research requires generalizable solutions for the viral families that pose risk
- Research activities that are fundamental to PP
  - Bio-surveillance and viral discovery
  - Fundamental research (pathogenesis, immunology, antigen design, delivery, reagents and assays)
  - Research and Development of vaccines, therapeutics and diagnostics
  - Mechanisms to produce and deploy rapidly interventions on global scale
- Science and technology can help solve many problems BUT we need consensus on global coordination, communication, and governance
- Equitable distribution of discoveries and manufacturing is critical to address local problems
become global

Process for prioritizing the world's greatest pathogen threats- Marie-Paule Kieny

Phase 1

Scientific Prioritization

- Process: 30 independent viral family and 1 bacterial Working Groups
  200+ international experts
- Output: Not shortlisted and shortlisted viral and bacterial families
  (incl. prototype pathogen(s))

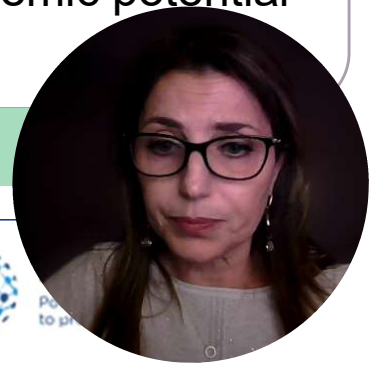
Dec 2022 – early 2024

Phase 2

Public Health Prioritization

- Process: Prioritization Advisory Committee (PAC)
  40 – 50 experts (including Chairs of WGs)
- Output: Final shortlist of viral and bacterial families with pandemic potential (incl. prototype pathogen(s)

Early 2024



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Strategies to promote collaboration and universal values- Phil Krause

- In addition to considering **speed and cost**, preparation for the next pandemic must consider **QUALITY, EQUITY, and TRUST** as essential values
- Preparations and implementation of pandemic response thus should be **country-centered, transparent, and collaborative**

- Target product profiles will need to consider outputs of the virus/pathogen family prioritization process, with an eye towards generalizability

- WHO will play an essential role in assuring a high quality, equi trusted global response

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Methods for Virus Detection and Discovery- Ian Lipkin

- **Capture sequencing**
  - Rapid, sensitive, inexpensive, straightforward platform for discovery, surveillance, and differential diagnosis
  - Sample Receipt to Pathogen Identification in less than 8 hours
  - Several new pathogens identified
- **Agnostic serological assays**
  - To detect footprint of past infections in the immune system, elucidate causes of outbreaks (e.g. AFM and ED 68) and provide early evidence of cross species transmission
  - Microarrays and Multiplex Phage Display
- **GAPP, the Global Alliance for Preventing Pandemics**
  - international collaborative public health research center to establishes sust
    infrastructure for infectious disease discovery, surveillance, diagnostics, ar
    response

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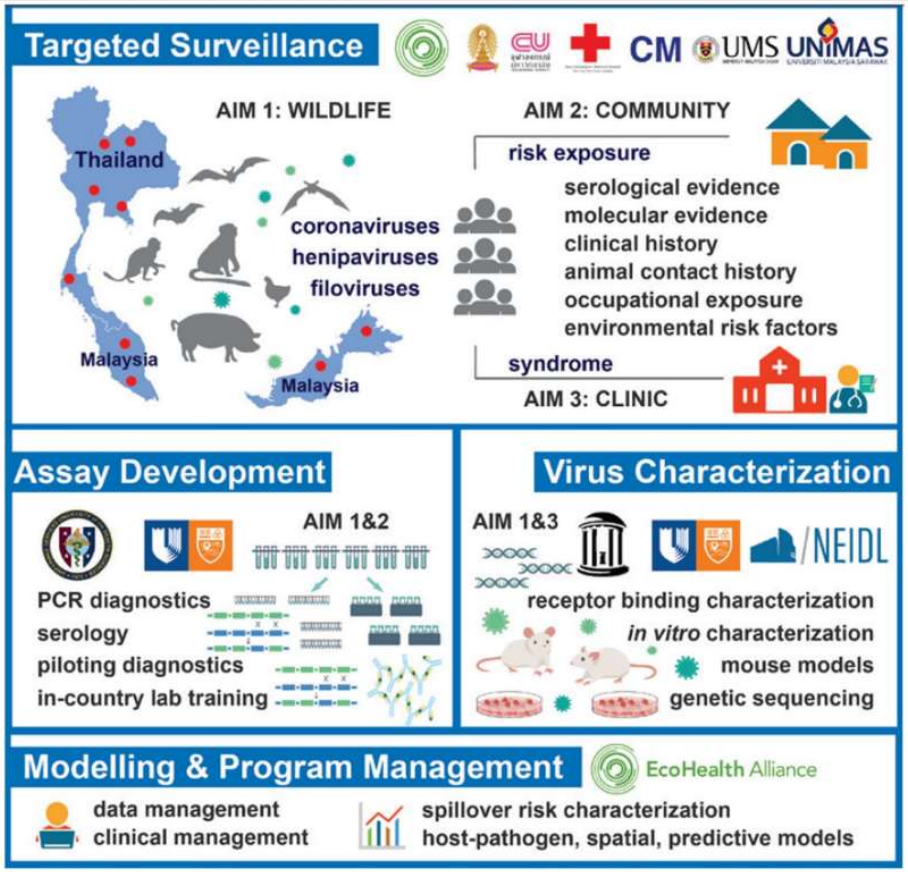
Smart Biosurveillance- Peter Daszak



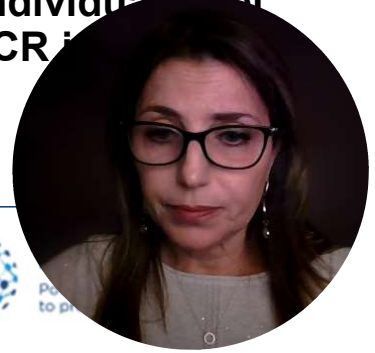
Environmental sampling

Advantages:

• Cost effective, Rapid • Convenient, Flexible • Wider net at high-risk interfaces • Biosafety, biosecurity • Animal welfare

Disadvantages:

• Sensitivity • Sample types • No individual level (meta/epi)data• Bioinformatics • PCR i… sample degradation• SOP



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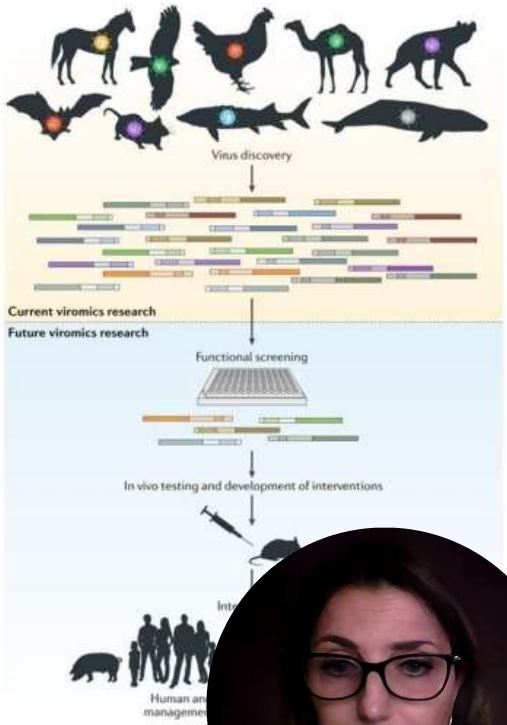
Understanding cell tropism and receptor requirements- Vincent Munster

- Wealth of genetic data, but limited full genome data
- Limited connection between surveillance / discovery and mechanistic work
- Mechanistic work currently limited by absence of generizable high throughput tools



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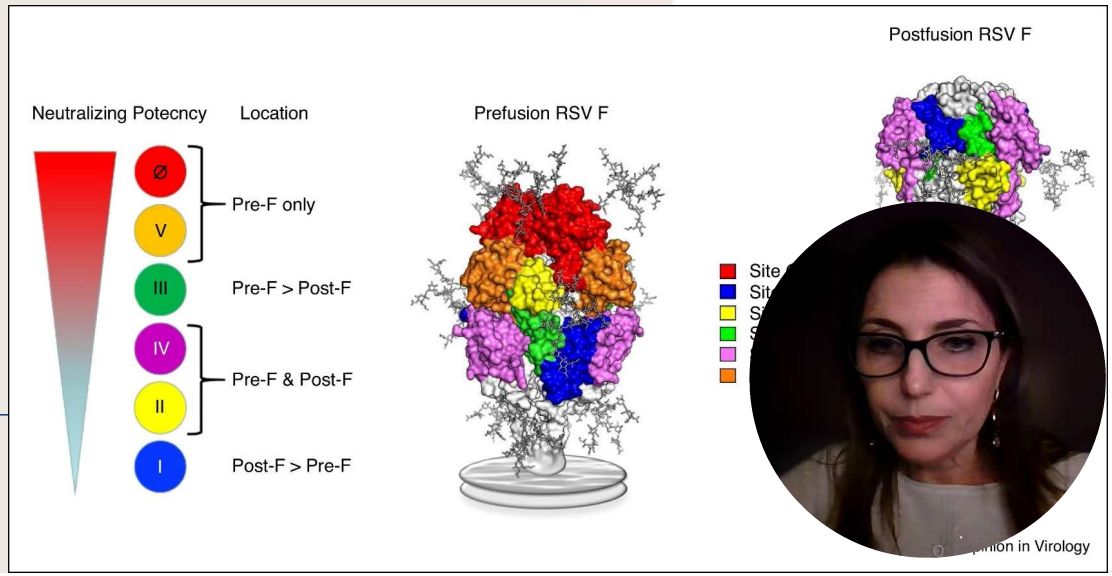
New Technologies to Define the Atomic-level Details of Surface Proteins Likely to be Vaccine Targets- Jason McLellan

- New advances in cryo-EM have enabled higher resolution and higher throughput than ever before
- High-throughput synthetic biology accelerates antigen engineering by enabling rapid design-build-validate cycles for many new protein designs
- AI/ML combined with high-throughput screening is allowing accelerated development of vaccine antigens for important human pathogens



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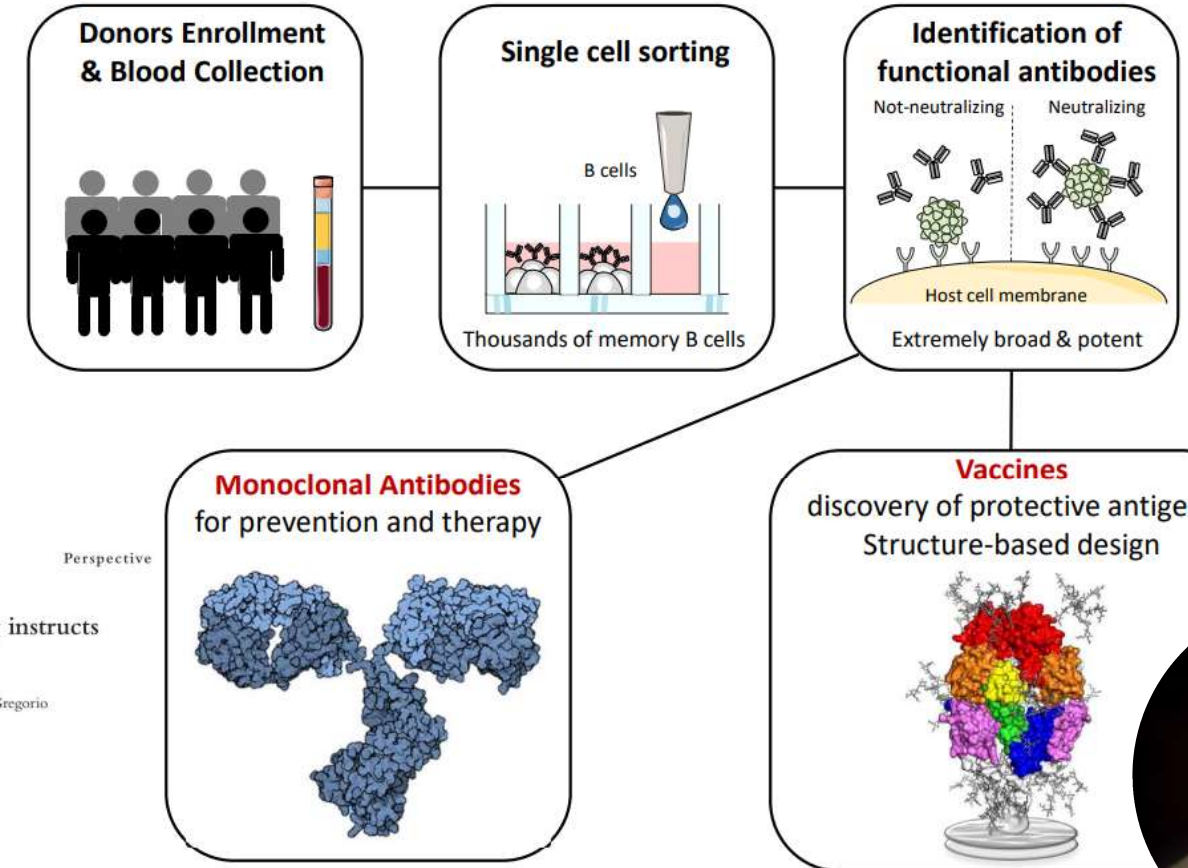
Rapid development of monoclonal antibody and protein reagents to guide and facilitate vaccine development- Emanuele Andreano

COVID mAbs were the first molecules to be discovered and approved for emergency use authorization (94 days from discovery to first human dose)



JEM Perspective

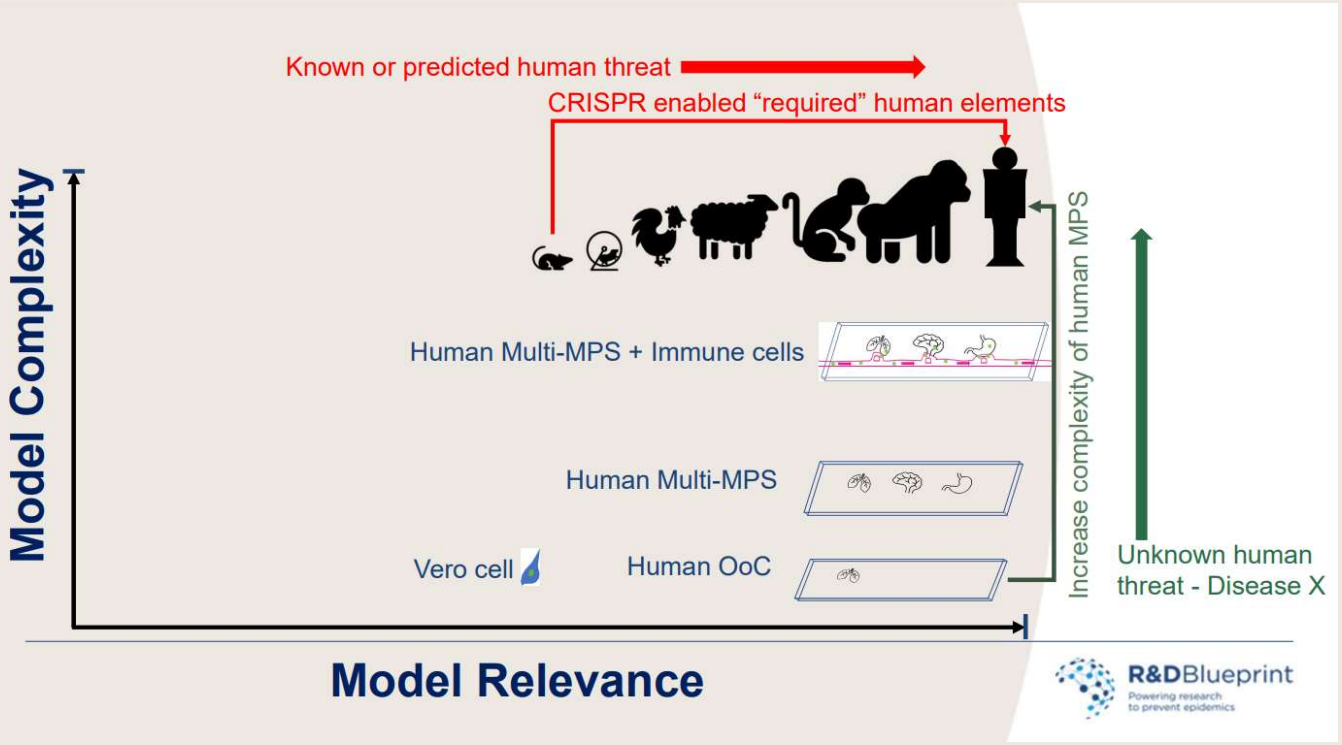
Reverse vaccinology 2.0: Human immunology instructs vaccine antigen design

Rino Rappuoli, Matthew J. Bottomley, Ugo D'Oro, Oretta Finco, and Ennio De Gregorio

GlaxoSmithKline Vaccines S.r.l., 53100 Siena, Italy

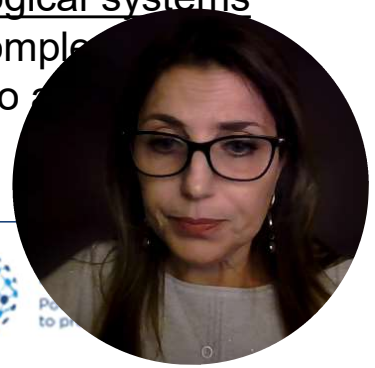
Modified from: Rappuoli R. et al. J Exp Med. 2016 Apr 4; 213(4): 469–481.; McLellan J. et al. Science. 2013 May 31;340(6136):1113-7

Developing humanized models with an eye on potential for generalizability- Simon Funnell, Mark Johnson, Lenny Schultz, Alexander Mosig, Alireza Mashaghi



Key needs

- Sharing data and resources, especially standards, reagents, pathology data, clinical samples and methodology
- Simultaneous development of animal models refined for each of the known high-risk groups of pathogens along with simultaneous development of microphysiological systems which may comple
support in vivo



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Developing immunological assays with an eye on potential for generalizability- Bill Dowling

- The WHO Assays working group was established to coordinate the development and standardization of immune assays to support vaccine development for COVID-19 , and then later for other WHO priority pathogens
- Continued sharing of protocols, methods and results will help to advance the development of immunoassays for Disease X vaccines
- Research done in advance of an epidemic or pandemic, as well as pre-established partnerships and processes, will shorten the time needed for implementation
- Use of novel, high throughput platform technologies applied to viral or bacteria will allow rapid adaptation to newly emergent pathogens

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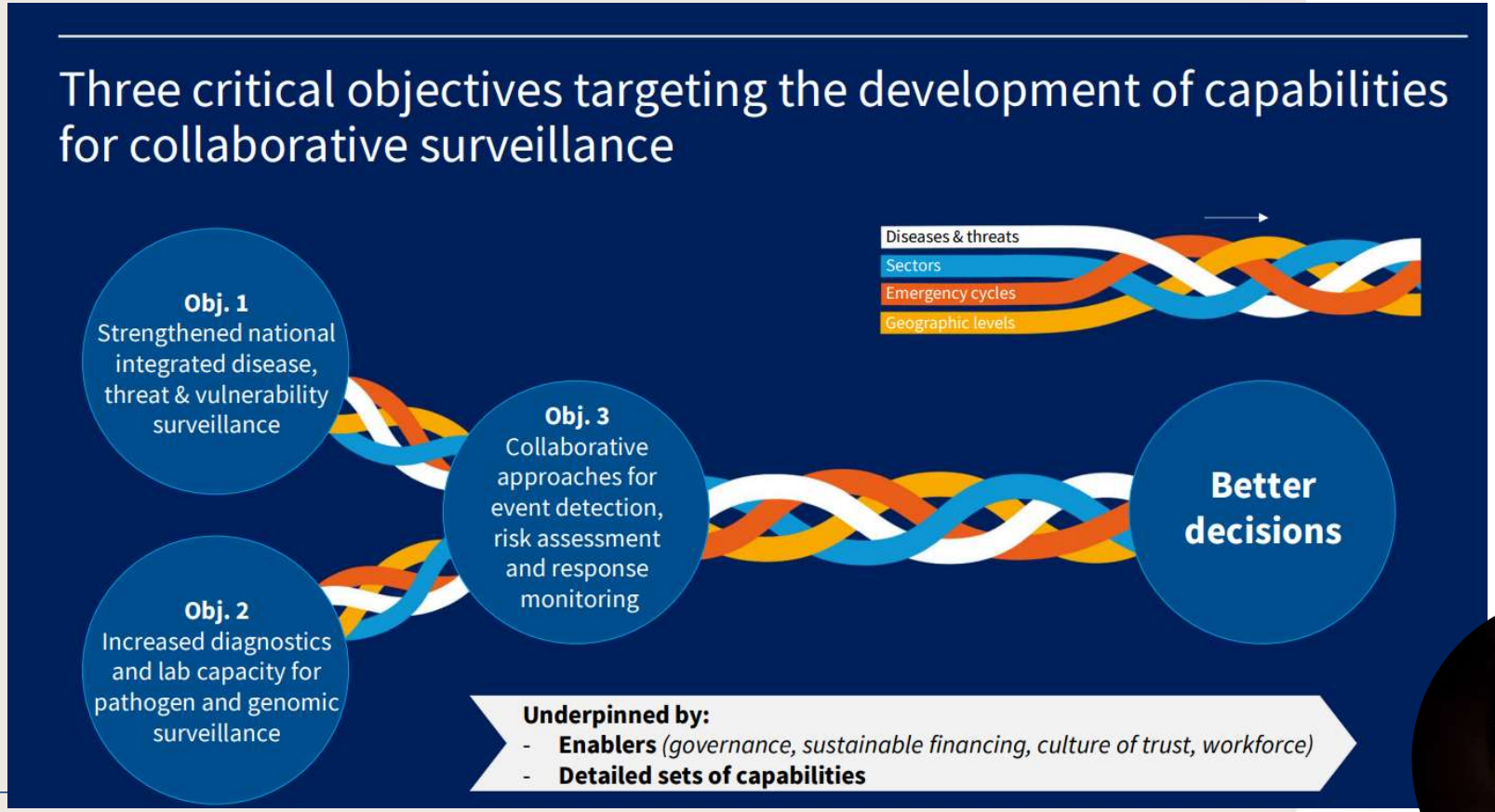
New Division & WHO Hub for Pandemic and Epidemic Intelligence- Sara Hersey



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An approach to fast-track assessment of candidate MCMs

and support pandemic prevention and control

1 Prioritization

WHO Independent expert process to prioritize candidate vaccines

A WHO process for prioritization of candidate vaccines by an independent WHO Technical Advisory Groups on candidate vaccine and treatments prioritization

2 Availability

Agreement on availability and access to candidate vaccines and therapeutics

Decisions are informed by outcomes of the prioritization process on minimum number of candidate product doses required for research during outbreaks and that need to be available.

3 Clinical trials

CORE protocols and platforms to promptly initiate trials with equitable access to research

Ministries and researchers in affected countries are in the driving seat and integrated into the response. CORE protocols for viral and bacterial families design and approved in advance

4 Agreements

Prior agreement on legal collaboration, insurance, indemnity and liability

A partnership model and signed agreements with Ministries of Health and developers with **access** to MCMs considered, and a framework for insurance and liability arrangements.

5 Funding

Access to readily available funding through committed financing mechanism

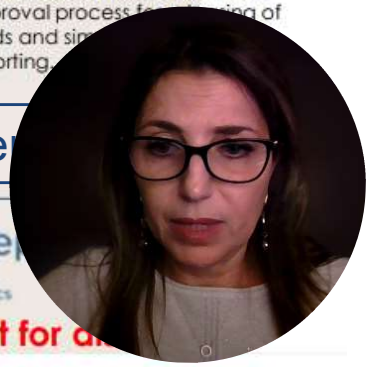
Signed agreements with contributors; aimed at a simple approval process f… of funds and si… reporting.

6 Collaborative approach

To foster an open flexible collaborative mechanism that allows a variety of contributors

Including pathogen and trial experts, local researchers, and outbreak response teams to help adjust and implement research as needed

Ana Maria He…



R&DBlue…
Powering research to prevent epidemics