WHO R&D Blueprint Update

progress and plans

March 2018

Why an R&D Blueprint?

Experience during the Ebola epidemics has demonstrated that it is possible to accelerate R&D during emergencies

BUT

R&D preparedness and effective collaboration frameworks should be accelerated in advance of any new epidemic

Operational objective of the Blueprint

Declaration of PHEIC emergency

Availability of effective diagnostics, therapeutics & vaccines

Day 0…I…I…I…I…I…I…I…I…I…I…I…I… Day available

The R&D Blueprint seeks to create an enabling environment through which all actors, through increased funding, data sharing and partnerships, can drive change in the public health landscape to provide an elevated level of global impact.

AN R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS

PLAN OF ACTION
MAY 2016

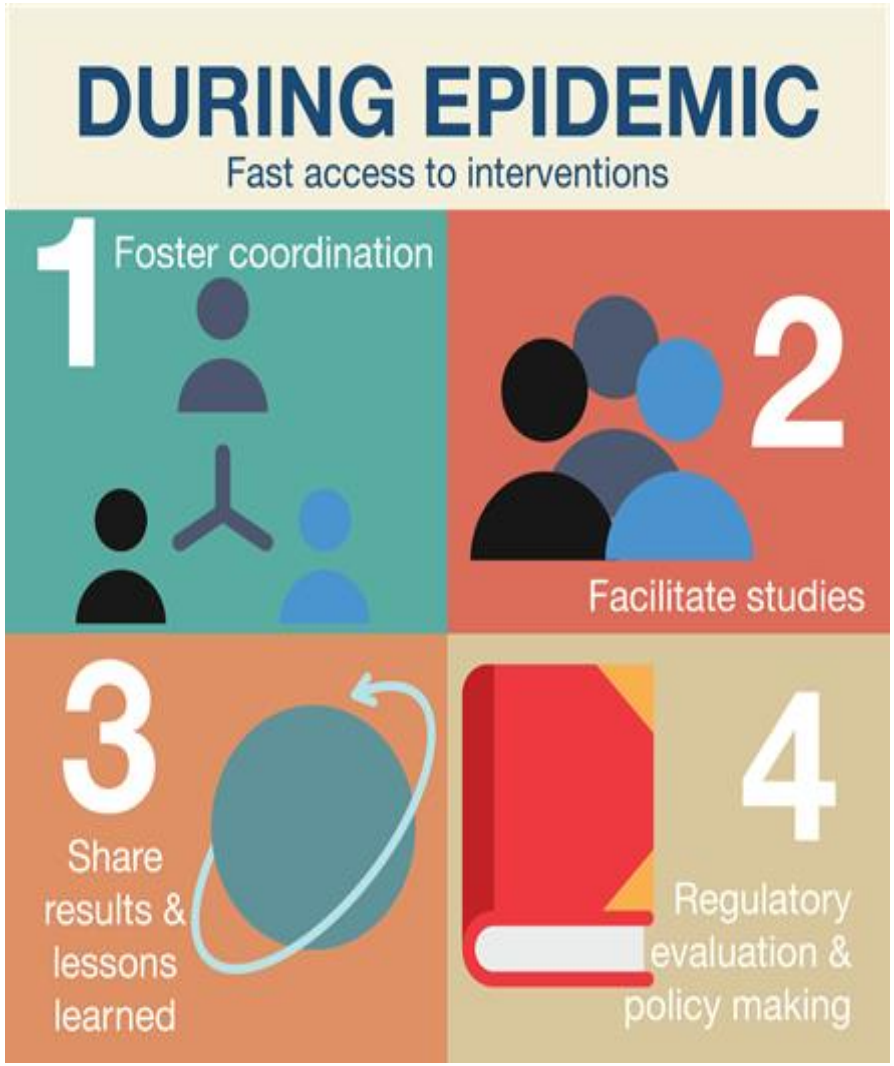
World Health Organization

A Improving coordination & fostering an enabling environment

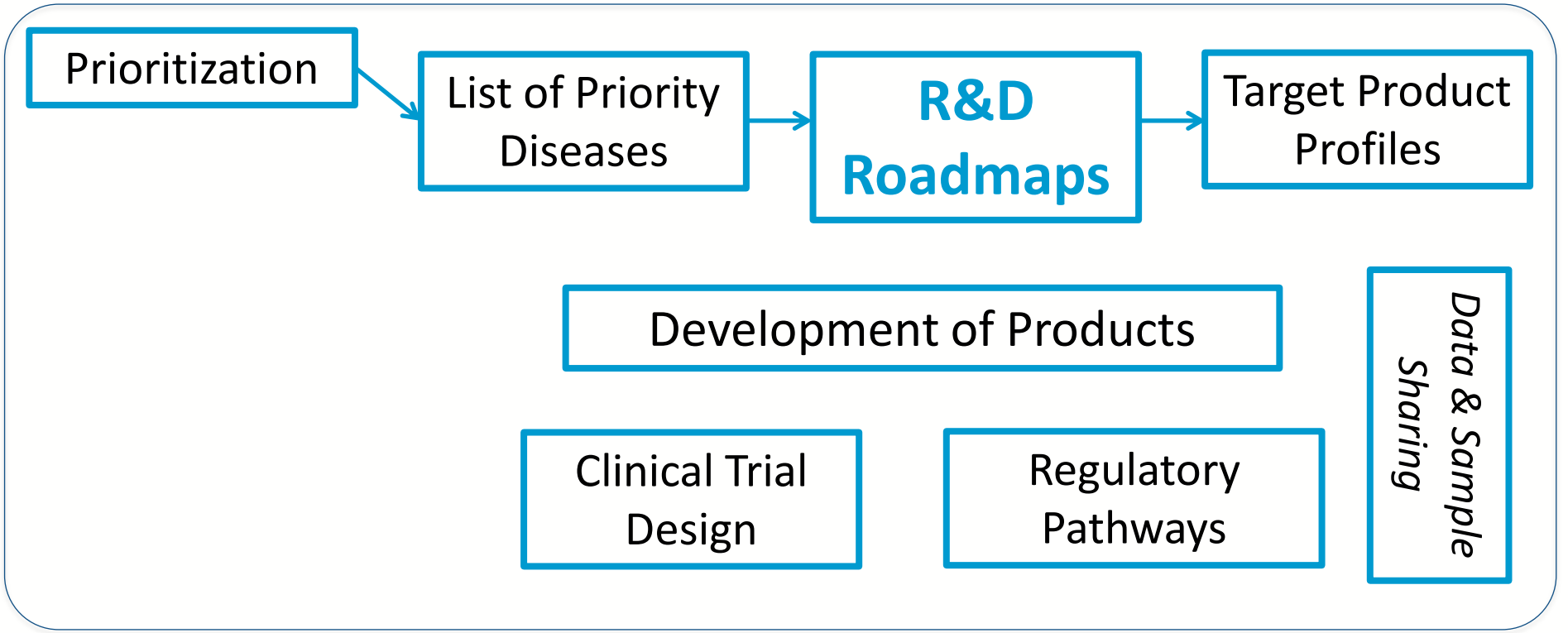
B Accelerating Research & Development processes

C Developing new norms & standards tailored to the epidemic context


BEFORE EPIDEMIC
Prepare for the inevitable
1 Governance & Coordination
2 Knowledge sharing
3 Assess threat & define priority pathogens
4 R&D Roadmap
5 Funding
Set regulatory pathway
6
Regulation
Ethics
Evaluation
7 Collaboration & Partnerships
8 Expand local capacity
LAB
Regulatory review & Policy development
9


DURING EPIDEMIC
Fast access to interventions
1 Foster coordination
2 Facilitate studies
3 Share results & lessons learned
4 Regulatory evaluation & policy making

R&D Blueprint overview



SAG
Scientific Advisory Group

GCM
Global Coordination Mechanism

M&E
Monitoring & Evaluation

Prioritization: List of priority diseases 2018

(The order of pathogens on this list does not denote any ranking of priority)

- Lassa Fever and other severe Arenaviral haemorrhagic fevers
- Crimean Congo Haemorrhagic Fever
- Filoviral pathogens (including Ebola and Marburg)
- MERS-CoV
- Other highly-pathogenic coronaviral pathogens (e.g. SARS)
- Nipah and related henipaviral pathogens
- Rift Valley Fever
- Severe fever with thrombocytopenia syndrome
- Zika

And any pathogen identified by the decision instrument

Chikungunya Virus continues to warrant further research and development.

R&D Roadmaps: A generic methodology

Developing and implementing R&D Roadmaps for priority pathogens with epidemic potential

R&D Blueprint roadmaps are forming a strategic framework that underpins strategic goals and research priorities of the global R&D community

↓

developed on the basis of

a **generic methodology**

purpose: to provide a standardized procedure that structures and harmonizes the development and implementation of R&D roadmaps

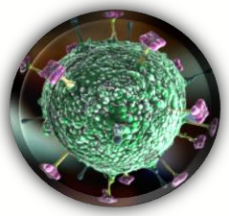
Cycle of review

- → Internal review – **completed**
- → Intermediate review – **completed**
- → External review – **ongoing**
- → Pilot testing for development of the following roadmaps (taskforce) – **ongoing**
  - Ebola/Marburg, Lassa and Nipah (CIDRAP)
  - CCHF (WHO)
  - Pathogen X (BMGF)

Target Product Profiles

	Circulation of draft TPP to Expert Working group for comments	Public consultation of draft TPPs	Final TPP published at WHO website
Monovalent Ebola – reactive and preventive use	✓	✓	2015 ✓
Multivalent filovirus vaccine TPP – preventive use	✓	Oct 2016 ✓	Nov 2016 ✓
Revised Zika virus vaccine TPP **(first version, published July 2016)**	✓	Dec 2016 ✓	Feb 2017 ✓
MERS Co-V vaccine TPPs (3)	✓	Feb 2017 ✓	May 2017 ✓
Nipah Virus vaccine TPP	Q1 ✓	Q1 ✓	✓
Lassa Fever virus vaccine TPP	Q1 ✓	Q2 ✓	✓

Global level



Nipah

Roadmap Mar 2018

Critical path for research and potential use
Criteria for candidate products prioritization
Dashboard progress (Taskforce)

TPP V 2017

Dashboard of candidate products vs TPPs
R&D Observatory

Generic protocols 2019

Deployment (outside trials) 2018

Non product research WHE/GOARN

No. of doses for Phase 2b/3 trials
Site selection
Modelling
Method. discussion

SAGE or STAC recommendations
Trained teams
Logistics
Coordination plan
Community engagement
Access to candidate products

GCM

Mapping of stakeholders

SAG / TAG

Recommendations priority research during event

WHE/IMS

Country level

NRAs + ERCs - AVAREF joint reviews of protocols

Support to countries for liability and compensation

Tools for review/design of trials at country level

Tools for data sharing and sample sharing

Basic capabilities: surveillance, lab, case management, …

Country Operational Emergency Plan

Determining number of doses GMP grade material

for trials and expanded access / compassionate use

Generic Protocols

Methods and design guidance
No. of doses for Phase 2b/3 trials
Site selection
Modelling

Study designs
Sample size calculations under various scenarios

→ *No of doses* (range under various scenarios)

Deployment (outside trials)

WHO recommendations
Approach under EUAL or Expanded Access/ Compassionate use

Target population
Geographic extension
Delivery strategy
Schedule

→ *No of doses* (range under various scenarios)

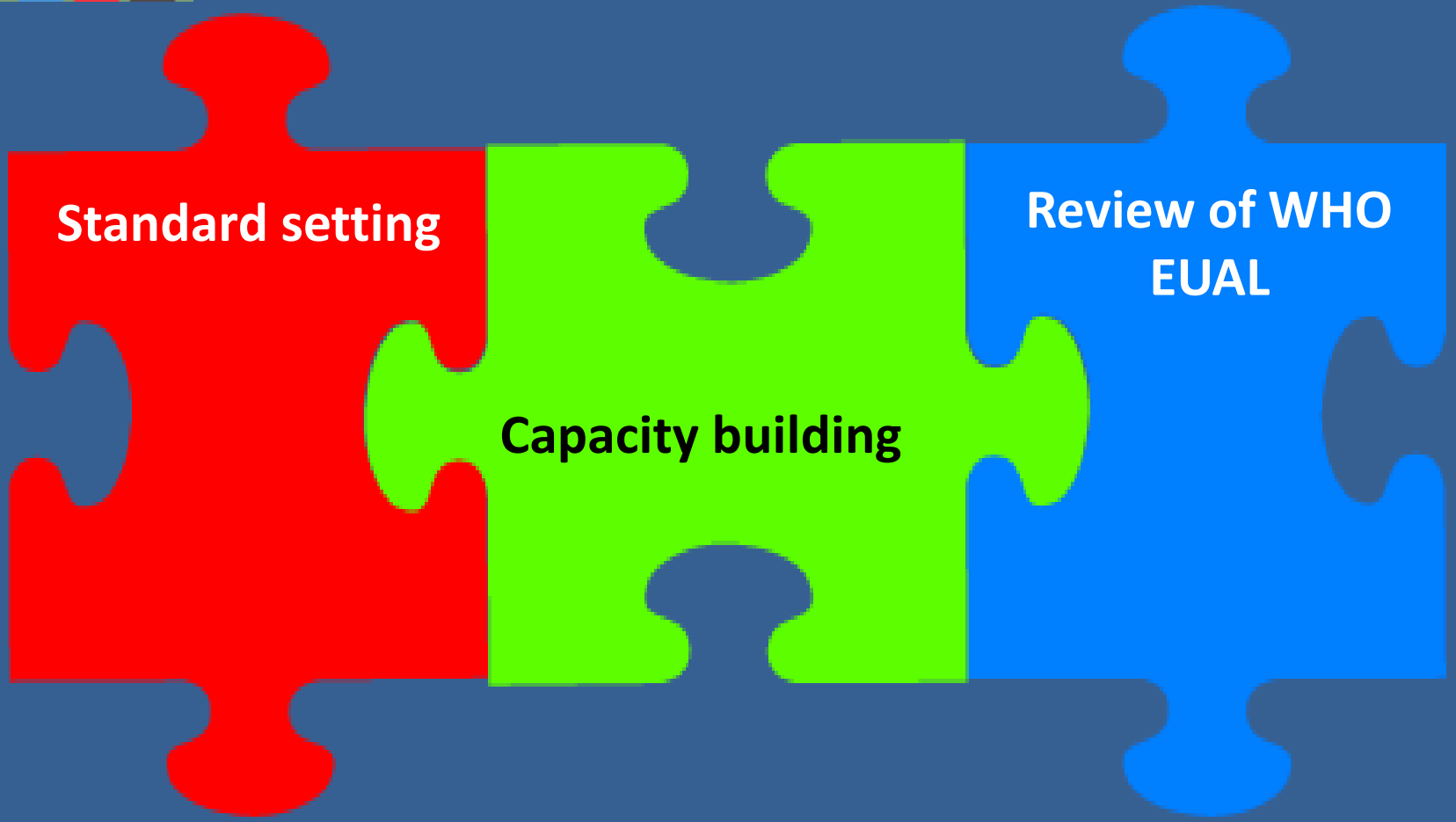
Supporting basic capacity

at country level

- NRAs + ERCs - AVAREF joint reviews of protocols
- Support to countries for liability and compensation (outside trials)
- Tools for review/design of trials at country level
- Tools for data sharing and sample sharing
- Basic capabilities: surveillance, lab, case management, …
- Regulatory guidance (see next slide)

Supporting regulatory capacity

at global, regional and country level



Global Coordination Mechanism (GCM)

A high-level strategic convening mechanism

to coordinate multiple interactions amongst key R&D partners
to better enable and support preparedness and support research.

Nov 2016

1st Scoping meeting
Need for a GCM
Initial ToRs
WHO requested to act as convener and as the Secretariat

March 2017

2nd meeting:
Review TORs
Discuss coordination issues re Zika vaccines

Nov 2017

3th Consultation:
Finalize TORs
Review Blueprint PoA and SAG recs
Research pillar & research response

Developing a **RESEARCH PILLAR** for the emergency response

Mapping of research capabilities at global & country level

Definition of ToRs and composition of the Global Coordination Mechanism

Finalize and test the process Adjust as needed

Mapping of stakeholders

Definition of ToRs and composition of needed independent advisory groups

Definition of SOPs guiding the interactions between the various bodies involved in the research and with the IMS

Consultative process with all stakeholders involved