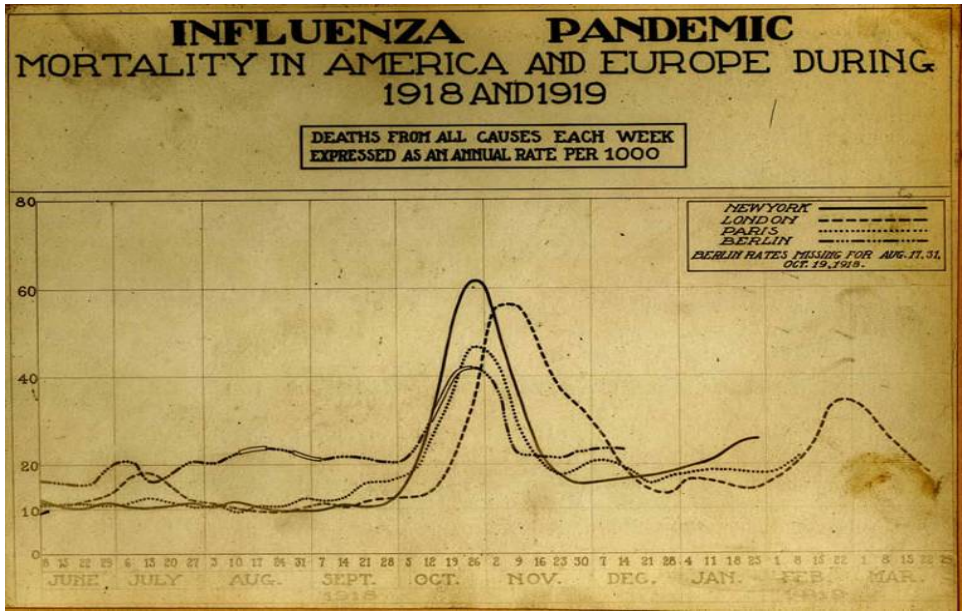
ISARIC

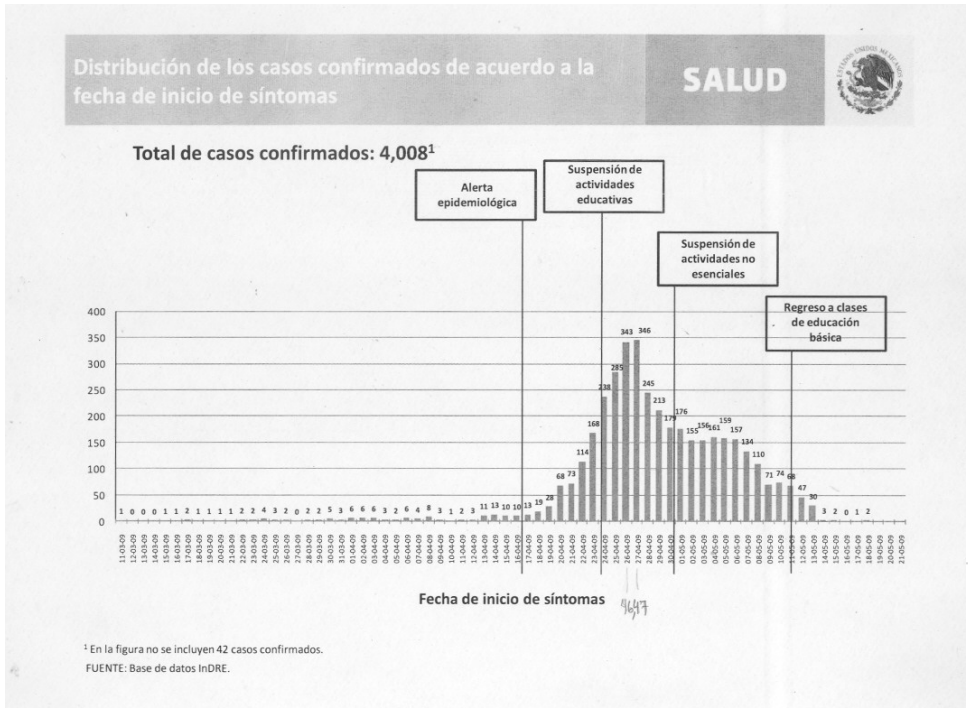
World Health Organization

The International Severe Acute Respiratory and Emerging Infection Consortium

ISARIC



1918



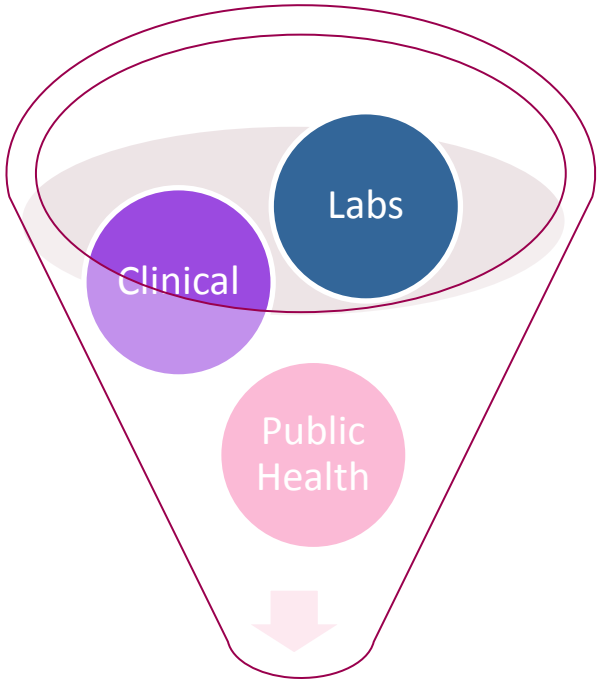
2009

ISARIC

Participants

100 Participants from
40 Countries in 6 Continents

- ICDDRB
- Institute Pasteur
- CCCTG CANADA & InFACT
- PERCH
- ANZAC ITU NETWORK & InFACT
- MOSAIC
- CDC USA
- SEAICRN
- World Health Organisation



The gap is in Clinical Research
ISARIC will fill that gap

ISARIC

Working Group 1 - Inter-pandemic clinical trials

This Working Group will develop candidate cross-Consortium studies based on both novel and traditional clinical trial designs that can be implemented in the inter-pandemic period. WG1 will lead the development of a minimum of three clinical trials for implementation in children and adults including low and middle income countries. Possible topics include but are not limited to: large pragmatic trials of community acquired pneumonia, immunomodulatory therapy in SARI, anti-viral therapy for influenza.

Go to Working Group

Working Group 2 - Global data collection and collation

This Working Group will complete a global inventory of existing databases related to SARI and pandemic H1N1 among ISARIC and InFACT networks, undertake standardisation and harmonisation of definitions, and develop on-the-shelf pandemic/novel threat response protocols. All partners and networks of ISARIC have agreed to share existing databases and work towards harmonisation of definitions to facilitate meta-analyses. This will include development of standards for tiered and minimal data sets that will be used for developing outbreak/pandemic protocols.

Go to Working Group

Working Group 3 - Geonomics, Pathogenesis and Pharmacology

This Working Group will develop pathogenesis studies aimed at understanding the dynamics of host responses, host genetic factors in susceptibility, virus/host interactions, and pharmacokinetic-pharmacodynamic relationships in treated patients. WG3 will

Working Group 4 - Changing clinical research paradigms for rapidly emerging public health threats

This Working Group will drive the critical evaluation of the barriers and the ethical framework required to facilitate the development of clinical research in response to a rapidly emerging health threat. WG4 will be assessing the ethics of clinical research

ISARIC

ISARIC

Home | About Us | Community | Resources | Working Groups | Contact Us | Follow Us

Resources

Singapore SARI BSP Documents

by Kajsa-Stina Longuère

ISARIC/WHO BSP sampling plan and CRF adapted by the Singapore Severe Acute Respiratory Infection Study Group, available for download.

11th July 2013 · 0 comments

PHE/ISARIC Decision Support Document

by Kajsa-Stina Longuère

The PHE/ISARIC Decision Support Document is a joint effort between ISARIC and Public Health England, and aims to serve as support to clinicans treating patients that have been confirmed positive with MERS-CoV (novel coronavirus). The document includes generous contributions research scientist, public health experts, and clinicians globally.

19th June 2013 · 0 comments

Newsletter May/June 2013

by The Editorial Team

May/June 2013 Newsletter

3rd June 2013 · 0 comments

ADMIT Workshop in India

by Paritosh Malavyia, Raffaella Ravinetto, Shyam Sundar

6th May 2013 · 0 comments

ISARIC and WHO SARI and Natural History Protocols

by Kajsa-Stina Longuère

ISARIC

Protocols
CRFs

ISARIC/WHO Severe Acute Respiratory Infection
Biological Sampling Study Version 2.5.2
By ISARIC Working Group 3

Choose historical version

TIER1 Single sample point
TIER2 Serial sampling moderate
TIER3A Sampling contacts
TIER3B Healthcare workers
TIER3C Pharmacology

Highlight tiers

Click to choose tiers above, select text (CMD-A), copy (CMD-C) then paste (CMD-V) each page into a new word processor document.

Create direct link to current settings.

Case record forms for use in the first 50 cases:
WHO New Outbreak Case Record Form
WHO New Outbreak Follow Up Form
WHO Data dictionary

Case record forms for use in subsequent cases:
ISARIC Core Case Record Form
ISARIC Supplementary Data Form
ISARIC Core Follow Up Form

Click here to log in to online data entry system

Intro | Summary | Protocol | Adult Info | Adult Consent | Consultee Info | Consultee Consent | Young Assent | Child Assent | Cartoon

ISARIC/WHO Severe Acute Respiratory Infection Biological Sampling Study

ISARIC

World Health Organization

17th May 2013. Version 2.5.2

Sponsor: [***Insert name of sponsor***]

Chief Investigator: [***Insert name of chief investigator***]

Co-Investigators: [***Insert names***]

Funder: [***Insert details***]

License.

Setting up research studies.

The World Health Organisation supports the conduct of investigator-led clinical research in outbreaks of emerging infection. In order to facilitate this, the following two options are recommended for the use of this research protocol:

- Use these documents independently of, and with no obligations to, WHO. Studies using this protocol will be compatible with other studies around the world, enabling future collaboration on data analysis as needed.
- Use these documents in collaboration with WHO and ISARIC to ensure rapid set up and analysis. ISARIC can help to link investigators to laboratories currently working on relevant analyses, and access to a secure online database for clincal data collection; WHO can provide additional resources in low- and middle-income countries to enable data and sample collection.

1. Background and Objectives

1.1 Purpose of the Document

ISARIC

http://www.prognosis.org/isaric/

Protocols | CRFs | Slideshow

ISARIC/WHO Severe Acute Respiratory Infection
Biological Sampling Study Version 2.5.3
By ISARIC Working Group 3

Choose historical version
Create direct link to current settings.

Click on these words to choose a tier and sampling intensity:

TIER1 Single sample point
TIER2 Serial sampling light
TIER3A Sampling contacts
TIER3B Healthcare workers
TIER3C Pharmacology

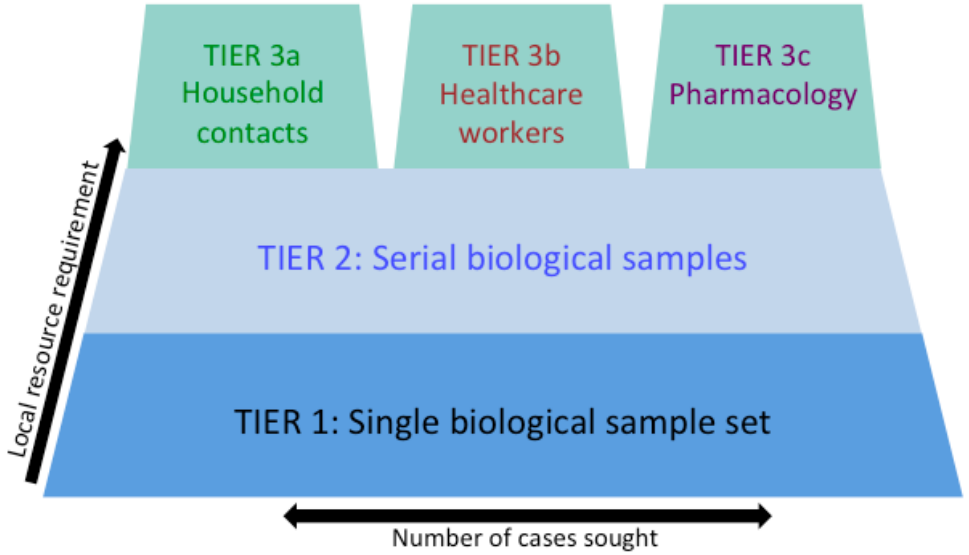
☑ Highlight tiers

Intro | Documents

ISARIC/WHO Severe Acute Respiratory Infection Biological Sampling Study
INTRODUCTION - HOW TO USE THIS PROTOCOL

ISARIC

World Health Organization

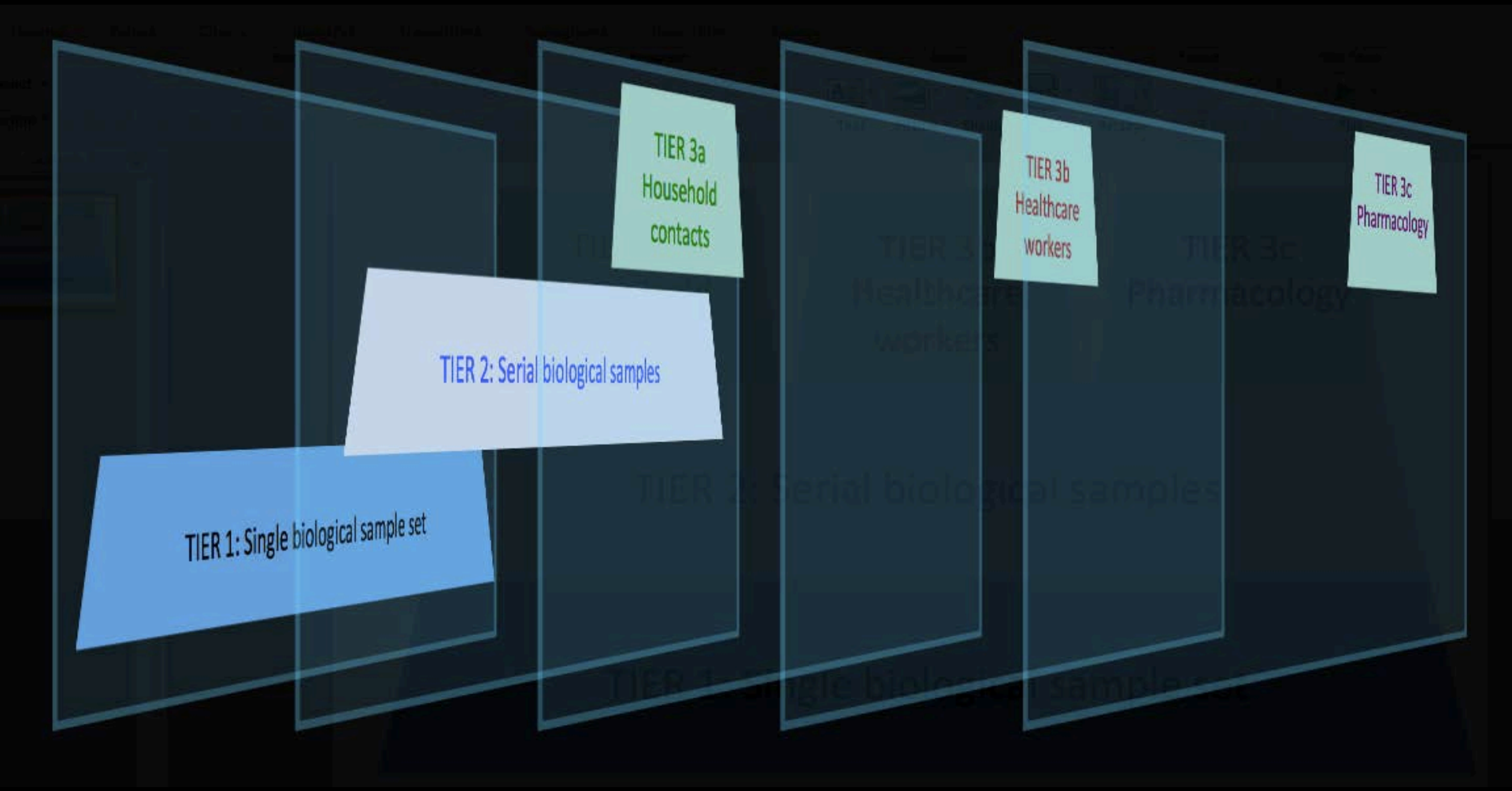


	Recruitment	Week 1						Week 2								Further samples	Convalescent samples
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		3 months
>40kg	R		S						S								C

R = recruitment samples. S = serial samples including pathogen samples; P = research pathogen samples only; C = convalescent samples (see protocol, Table 3).

ISARIC

Adaptable to needs/resources



		Serial samples.															
	Recruitment	Week 1						Week 2								Further samples	Convalescent samples
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		3 months after recruitment
>40kg	R		S						S								C
20 to 40kg	R		S						S								C
10 to 20kg	R		S						S								C
4 to 10kg	R		S						S								C
>4kg	R		S						S								C
Sample priority	1		2						3								4

R = recruitment samples. S = serial samples including pathogen samples; P = research pathogen samples only; C = convalescent samples (see Table 3). In the event that local resource limitations require sampling frequency to decrease, samples will be prioritised as shown (1=highest priority).

		Serial samples. Continue until resolution of acute illness*															
	Recruitment	Week 1						Week 2								Further samples	Convalescent samples
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Weekly until max 100 days	3 months and 6 months after recruitment
>40kg	R	P	S	P	S	P	S	P	S	P	S	P	S	P	S	S	C
20 to 40kg	R	P	S	P	S	P	S	P	S	P	S	P	S	P	S	S	C
10 to 20kg	R	P	S	P	S	P	S	P	S	P	S	P	S	P	S	S	C
4 to 10kg	R	P	S	P	S	P	P	P	S	P	P	P	S	P	P	S	C
>4kg	R	P	S	P	S	P	P	P	S	P	P	P	S	P	P	S	C
Sample priority	1	11	2	11	5	11	7	11	3	11	8	11	10	11	9	6	4

July 11, 2013

Singapore SARI BSP Documents

BY *Kajsa-Stina Longuère*

The Singapore Severe Acute Respiratory Infection Study Group has adapted the ISARIC/WHO Biological Sampling Protocol (V2.3.1 23 April 2013) for use in Singapore. The objectives of the study is to characterise aetiology, clinical course and complications and response to the treatment of SARI, and to identify biomarkers and correlates to further the understanding of SARI. The protocol will be implemented in 5 sites in Singapore. For more details, please contact Dr Ng Oon Tek: oon_tek_NG [at] ttsh.com.sg

USEFUL RESOURCES

Singapore SARI Study Group/ISARIC Sample Collection Plan *97.0 KB*

Singapore SARI Study Group/ISARIC CRF for SARI BSP *266.0 KB*

RELATED ARTICLES

UK

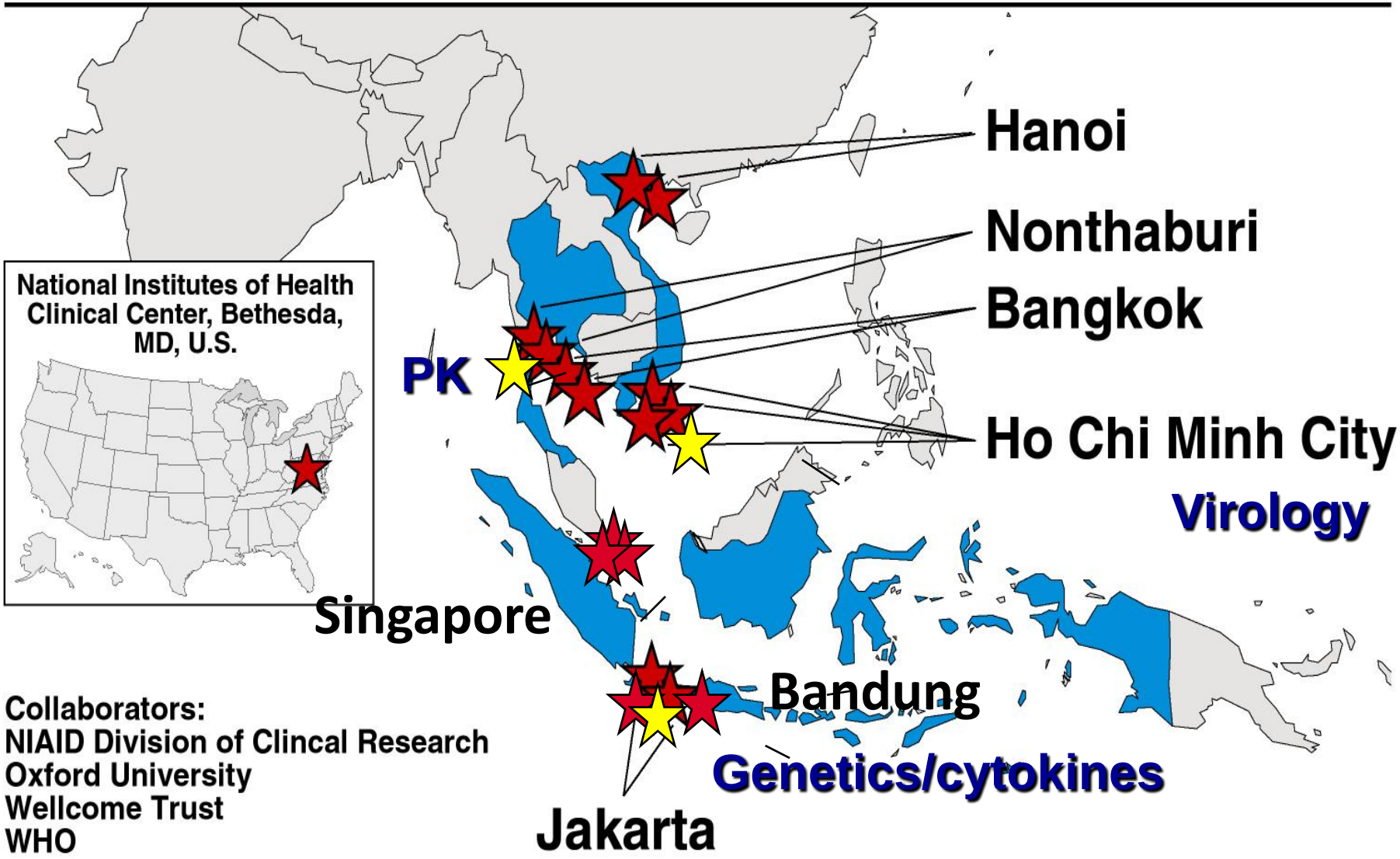
VIET NAM

CHINA – BEIJING / SHANGHAI

ISARIC

SEA Influenza Clinical Research Network

ISARIC associated Asian Network



ISARIC associated European Network

Theme HEALTH

Guide for Applicants: *Collaborative projects part B - stage 2*
Annexes specific to call: FP7-HEALTH-2013-INNOVATION-1

Proposal full title:

Platform foR European Preparedness Against (Re-)emerging Epidemics

Proposal acronym:

PREPARE

Type of funding scheme:

Collaborative Project (large-scale integrating project)

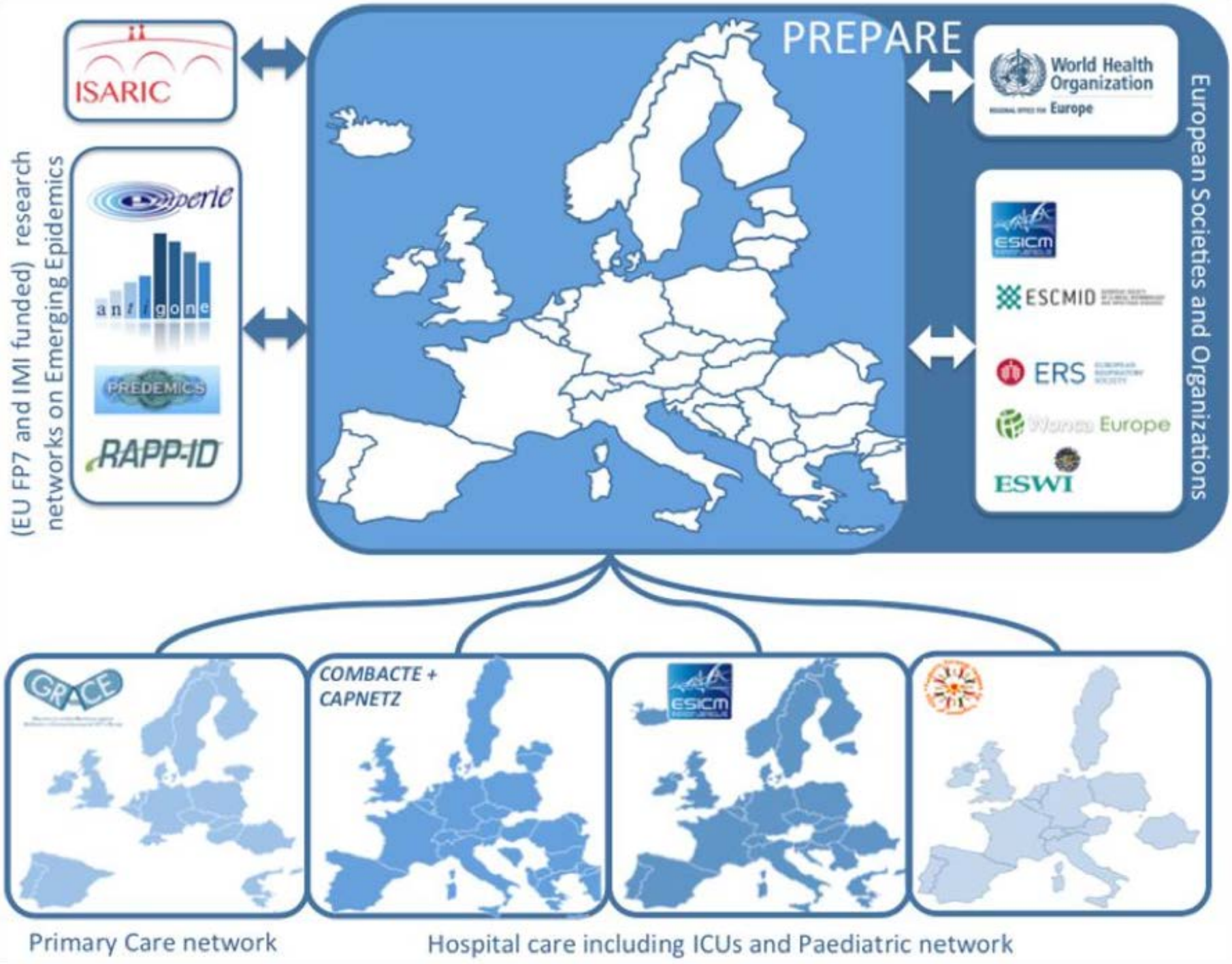
Work programme topics addressed:

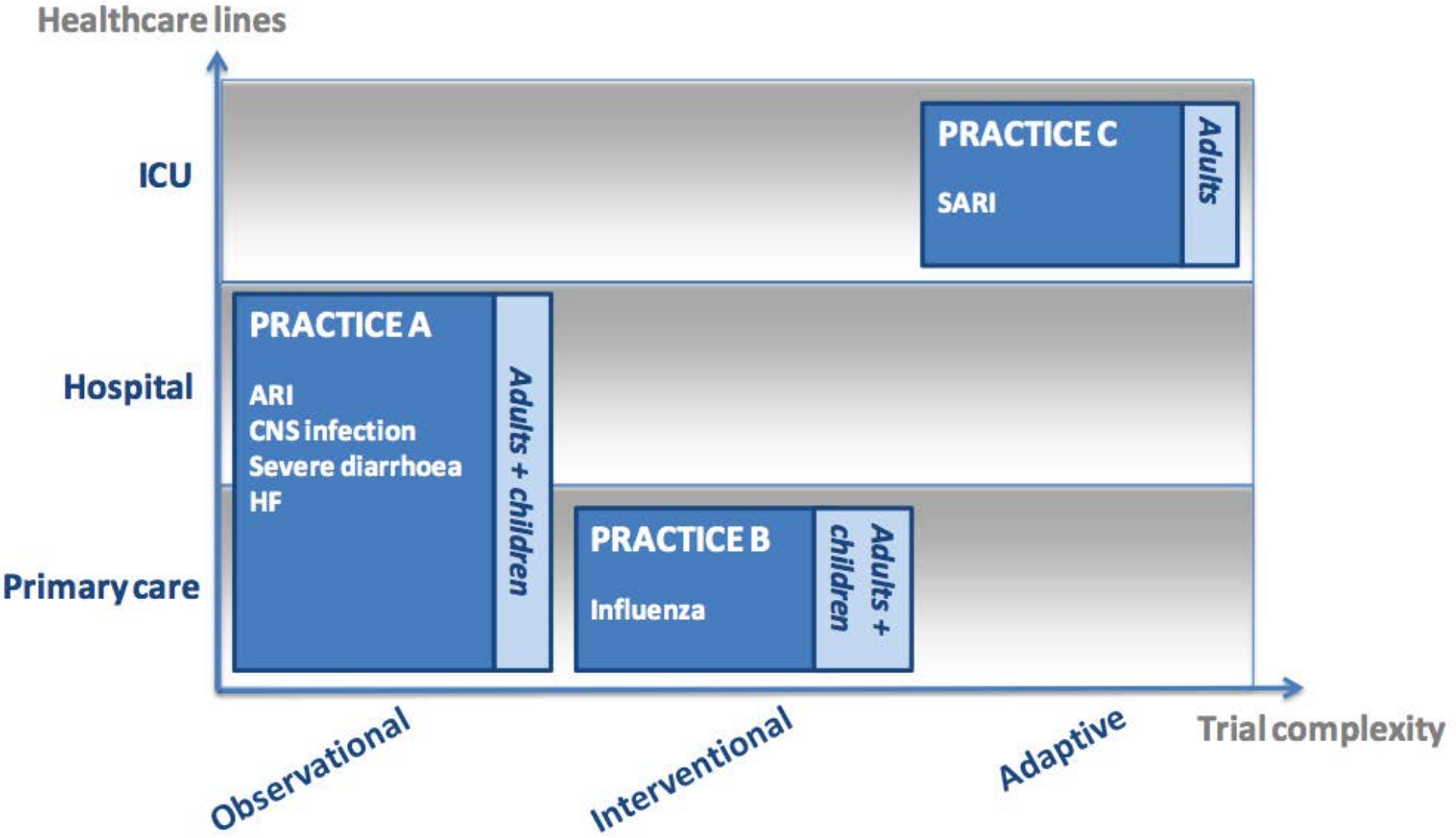
HEALTH.2013.2.3.3-1: Clinical management of patients in severe epidemics. FP7-HEALTH-2013-INNOVATION-1.

Name of the coordinating person:

Prof. Dr. Herman Goossens

ISARIC


ISARIC
(EU FP7 and IMI funded) research networks on Emerging Epidemics
Discerne
antigone
PREDEMICS
RAPP-ID
PREPARE
World Health Organization
Europe
European Societies and Organizations
ESICM
ESCMID
ERS
Women Europe
ESWI
GRACE
COMBACTE + CAPNETZ
ESICM
Primary Care network
Hospital care including ICUs and Paediatric network


Healthcare lines
ICU
Hospital
Primary care
PRACTICE C
SARI
Adults
PRACTICE A
ARI
CNS infection
Severe diarrhoea
HF
Adults + children
PRACTICE B
Influenza
Adults + children
Observational
Interventional
Adaptive
Trial complexity

ISARIC

WP number	3	Start date or starting event:	M1			
WP title	PRACTICE A: European Multi-centre standardised observational and natural history clinical data study in hospitalised and community patients (children and adults) with acute respiratory infection, severe illness caused by central nervous system infections, diarrhoea, or hemorrhagic fever					
Activity type	RTD					
Participant number	1	5	6	7	**8**	10	21
Participant short name	UA	ESICM	EMC	Imperial	**OxU**	SERGAS	PENTA
Person-months per participant	6	13	11	13	**65**	30	18

Objectives

- To prospectively study incidence, risk factors and clinical impact of infections with epidemic potential in Europe with an initial focus on acute respiratory infections, central nervous system infections, severe acute diarrhoea, hemorrhagic fever in hospitalised and PC patients;
- To collect prospective standardised observational and natural history clinical data from hospitalised and primary care patients (3000 adults and 2250 children) with acute respiratory infection (n= 1800) and from patients with severe illness caused by central nervous system infections (n= 1500), severe diarrhoea (n=1500), and hemorrhagic fever (n=450)
- To collect geographically-representative age-stratified population serum and acute-patient samples in these cohorts.

ISARIC

NETWORK OF COHORTS?

Vietnam

Hong Kong

Guangdong

UK

Peru

?

Comparable results? / assay performance / new insights

ISARIC