



ESF Science Meeting, Brussels, Belgium, 28 November 2013

PREPARE Meeting 2013

Scientific report

Summary

TRACE (partners) are involved in PREPARE (Platform foR European Preparedness Against (Re-) emerging Epidemics; www.prepare-europe.eu) granted for funding within the 7th Framework Programme Call Innovative health research 2013 of the European Commission (HEALTH.2013.2.3.3-1. Clinical management of patients in severe epidemics. FP7-HEALTH-2013-INNOVATION-1) and coordinated by the TRACE coordinator.

Currently, there is no coherent framework for the rapid implementation of cross-border harmonised clinical research studies in the event of an emerging epidemic. However, such studies are needed to provide clinical evidence in support of optimal patient management. At present, the field essentially needs to start from scratch during each new epidemic in recruiting sites, developing protocols, obtaining ethical and regulatory approvals, training clinicians and recruiting patients. Moreover, established networks that do manage to implement clinical trials at the earliest stages of an epidemic are typically restricted to regional or national levels, not covering the required breadth and size of patient groups necessary to draw useful clinical conclusions. The PREPARE project has been designed to address the bottlenecks of implementing timely clinical research in response to emerging epidemics. It establishes a network of networks, that combines common procedures and systems and “on the shelf” validated and pre-approved protocols with a clear governance structure to initiate immediately large scale pan-European clinical research studies addressing key clinical questions in the event of an emerging epidemic.

PREPARE will achieve this by 1) overcoming current ethical and regulatory hurdles for rapid approval of clinical research, 2) consolidating a pan-European network and infrastructure that supports coordinated international clinical collaboration and data exchange, 3) designing a new clinical research practice that is tuned to the nature of epidemics, and allows rapid large-scale internationally harmonised research, 4) developing supportive SOPs that are internationally recognised and 5) training network staff to implement these SOPs when needed. The inter-pandemic research programme will result in the following valuable output: 1) insights into current impact, etiologies and management of relevant infectious disease (ID) syndromes in Europe, 2) evidence-based guidance documents for the clinical management of ID, 3) pathophysiological insights to guide development of personalised clinical management strategies of ID, 4) whole genome mapping and sequencing outbreak tools, and 5) innovative point-of-care diagnostics.

In the new state-of-the-art evidence-based arena, international clinical trials of meaningful statistical power can start days after an outbreak has been detected and in clinically-relevant time span produce the insights needed to assess public health risks, to diagnose and stratify patient groups, to select optimal treatments and treatment regimens and importantly to effectively distribute this knowledge in and beyond European healthcare organisations. In addition, the insights and developments generated during intra- and inter- pandemic periods allow the development of novel preventive and therapeutic personalised clinical management strategies relevant for current clinical practice and potential future outbreaks. Thus far, no organisation or network in Europe has been able to build the infrastructure required for this endeavour. PREPARE will lay the foundations for a new paradigm in clinical management of patients in ID pandemics thereby reducing the public health-and economic damage.

In this PREPARE meeting PREPARE partners discussed the project management, the (changes in) leadership of several Work Packages, the composition of the PREPARE Advisory Board and Ethics Board, the preparation and status of the clinical networks and studies and the collaboration with external networks.

Description of the scientific content of and discussions at the event

Herman Goossens welcomed all present and gave a presentation introducing the main outline of PREPARE and whilst doing so provided everyone present to shortly introduce themselves (and their main role in PREPARE).

Project management aspects.

Frank Deege presented the essentials on project management in PREPARE focusing mainly on the budget aspects.

Work Package leadership (changes).

WONCA (represented by Janko Kersnik) and ESWI (represented by Chris Vanlangendonck) presented their goals, activities and structure. Together with ESICM and ERS it is the intention that these four European societies will jointly shape and implement the training activities in WP9 CREATE. A decision on who will take on the role of WP9 Coordinator cannot yet be taken. However, it is the intention that this role is given to ERS considering their experience and expertise in the training activities foreseen in WP9. ERS will discuss this internally and come back to this in the short term to the PREPARE project management team.

Peter Horby of P8 UOXF will be the new WP2 and WP3 Coordinator instead of Jeremy Farrar, who has been appointed Director of the Wellcome Trust.

The PRACTICE Coordination Team (PCT) will be chaired by Chris Butler (WP4) and co-chaired by Peter Horby (WP2, WP3) and Alistair Nichol (WP1). Other members remain unchanged (see Project Quick Guide). The composition and management of the PCT will be evaluated over time. A concern is that WP6, 7 and 8 are not represented in the PCT.

Several items have been agreed to be discussed at a teleconference in December and a F2F PCT meeting in January.

PREPARE Advisory Board and Ethics Board.

An inventory was made across all present on persons to be put on the shortlist for the PREPARE Advisory Board (PAB) and the Research Ethics Advisory Board (REAB).

Preparations and status of clinical networks and studies (PRACTICE studies (WP1-WP5)).

Alistair Nichol presented WP1 EARL. The WP1 team (Alistair Nichol, Chris Butler, Steve Webb) has been working on preparing the staffing of the project and planning the main immediate short-term actions. They are all well prepared to have a flying start in PREPARE but are dependent also on the active collaboration of all the other PREPARE members. An important consideration that should be addressed in WP1 is how to deal with the interests of and roles of the national health agencies during an epidemic. They could form an important hurdle in the rapid implementation of clinical studies.

Chris Butler presented WP4 PRACTICE Study B. WP4 has also been active in preparing for PREPARE. Several team meetings have been held including meetings with WP3. A Job description for the trial manager has been developed. The trial has been presented to the OUXF trial unit and the TRACE Steering Committee.

A short discussion follows whether or not we should not focus the WP4 PC study on another new antiviral instead of Oseltamivir, as this drug will shortly become generic. However WP4 team is convinced that the outcome will have practical value, as this is the first of its kind study in a pragmatic PC setting. Ab Osterhaus states that he is involved in new metadata analyses, which could be of interest to WP4. Also, Marion Koopmans points out that it could be interesting to also look at resistance development. This may require adjustments to the protocol. Chris Butler takes note of these suggestions.

Herman Goossens presented the status of COMBACTE and ESICM networks. Because of the absence of Marc Bonten and Jean-Daniel Chiche, Herman Goossens presents some slides on the status of both networks.

Federico Martinon Torres presented the status of the PENTA and SERGAS networks.

Based on these presentations the group comes to the conclusion that it is imperative that the WPs 1-5 will liaise frequently and intensively to ensure that full use is made of completed or ongoing exercises and that the cross network alignment is ensured. Examples discussed are making use of existing exercise in the area of CRFs and feasibility questionnaires for the network sites.

The appropriate body to discuss the alignment of activities across WPs 1-5, across the five networks (COMBACTE, ESICM, GRACE, CAPNETZ, PENTA and SERGAS) and between the paediatric perspectives and adult perspective is the PRACTICE coordination team.

Collaboration with external networks.

Yazdan Yazdanpanah of INSERM presented the nationally funded REACTing network, which can essentially be seen as the French equivalent of PREPARE. The complementarity between REACTing and PREPARE is evident, not in the least from a geographical point of view. Mock exercises could be aligned as well as the modelling component in REACTing which (together with the modelling work done in EMPERIE, PREDEMICS and ANTIGONE) could be of added value to PREPARE.

Gail Carson of P8 UOXF presented the ISARIC network. ISARIC was at the roots of PREPARE and the ties between ISARIC and PREPARE are embodied by the leading roles of ISARIC members in PREPARE (Menno de Jong, Alistair Nichol, Steve Webb, Jean Daniel Chiche, Derek Angus, Gail Carson, Peter Horby, Peter Openshaw, Jake Dunning, Gernot Rohde, Sylvie van der Werf).

Herman Goossens presented the Australian proposal for a pandemic preparedness network where Steve Webb is involved. All agreed that collaboration with the "Australian PREPARE" will be pursued by PREPARE, involving

- Inviting PREPARE collaborators to one or two focused workshops for the purpose of scoping unmet needs and further developing the research agenda;
- Harmonisations of definitions and protocols as much as possible to aid national comparison and facilitate participation in global scale information gathering efforts in a pandemic event: link with WP1 (EARL) and invite Alistair to SAB;
- Modelling to inform policy, both through pre-emptive consideration of alternative scenarios, and real-time estimation to inform the evolving picture.

Herman Goossens closed the meeting and thanked all present..

Assessment of the results and impact of the event on the future directions of the field

Most importantly, an events like this, supported by the European Science Foundation through TRACE, has the potential to impact substantially on the development of new translational research on antimicrobial resistance and community acquired infections in Europe and beyond. The meeting greatly increased the chances of delivering a successful international research project granted for funding within the 7th Framework Programme Call Innovative health research 2013 of the European Commission (HEALTH.2013.2.3.3-1. Clinical management of patients in severe epidemics. FP7-HEALTH-2013-INNOVATION-1) and coordinated by the TRACE coordinator.

If successful, PREPARE aims to establish a pan-European clinical research network and infrastructure for immediate 'on-demand' implementation of harmonised, large-scale clinical research studies in the context of emerging infectious outbreaks with pandemic or epidemic potential and provide the necessary evidence base for an optimal clinical management response.

Annexes: programme of the meeting and full list of speakers and participants.

Annex I

Meeting programme

PREPARE Meeting 2012, Brussels, Belgium, 28 November 2013

Agenda PREPARE Meeting

27 November 2013

Arrival of participants

28 November 2013

09.30 - 09.40 Opening and welcome (Herman Goossens*)

09.40 - 09.50 Introduction of all participants

09.50 - 10.20 Overview of PREPARE project (Herman Goossens*)

10.20 - 10.50 Present PREPARE budget (Frank Deege)

10.50 - 11.10 Discussion

11.10 - 11.30 Coffee / tea break

11.30 - 12.00 Clinical trial preparation (Chris Butler*, Theo Verheij,* Mike Sharland)

12.00 - 12.30 PREPARE Advisory Board (PAB) and partners (Herman Goossens*)

- Replace tasks of Jeremy Farrar
- Replace WHO Europe as a partner
- Select members PAB

12.30 - 13.30 Lunch break

13.30 - 14.00 Discuss extensively WP1 (Alistair Nichol)

14.00 - 14.30 Present Quick Guide (Frank Deege)

14.30 - 15.00 Prepare agenda kick-off meeting (All)

15.00 - 15.20 Coffee / tea break

15.20 - 15.40 Open call for proposals Horizon 2020 (All)

15.40 - 16.00 Any other business

* scientists affiliated with institutions funding TRACE

Annex II**List of speakers and participants***

1	UA	Herman Goossens; Greet leven, Inge Dierynck, Jasmine Coppens
2	AMC	Menno de Jong
3	CU	Chris Butler
4	UMCU	Theo Verheij, Frank Leus
5	ESICM	-
6	EMC	Marion Koopmans, Ab Osterhaus, Pieter Fraaij, Frank Deege
7	Imperial	Peter Openshaw
8	UOXF	Peter Horby, Gail Carson, Chris Butler
9	CAPNETZ	Grit Barten
10	SERGAS	Federico Martinon Torres
11	HLA	Charles Auffray
12	IP	Sylvie van der Werf
13	UoS	Ozren Polaszek
14	NIUD-UCD	Alistair Nichol
15	Biocartis	Patrick van den Bogaard
16	Biomax	Dieter Maier
17	Janssen	Jorge Villacian, Laurence Rimsky, Andre Capt,
18	BioMérieux	Alex van Belkum
19	UK-Bonn	Christian Drost
20	PENTA	Carlo Giaquinto, Mike Sharland, Julia Bielicki
21	UWA	-
22	ERS	Tanja El Nemr
23	ESWI	Chris Vanlangendonck, David de Pooter
24	WONCA	Janko Kersnik