PREPARE NEWSLETTER

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PREPARE kick-off meeting Antwerp - February 2014

In this issue

Editorial

Herman Goossens, PREPARE Coordinator, University Hospital and University Antwerp

In recent years several epidemics have posed considerable threats to public health, in Europe and beyond. The clinical research response to these epidemics has all-too-often proven to be fragmented, cumbersome and too delayed to generate data in time to provide evidence for clinical management of patients and for informing public health responses.

The PREPARE ("Platform for European Preparedness Against (Re-) emerging Epidemics") project has been funded by the European Commission and kicked-off in Antwerp in February 2014 to address this startling challenge. PREPARE's ambitious goal is to revolutionise the clinical research response to future epidemics and pandemics. More than 600 GPs in primary care and over 700 hospitals in Europe are integrating with Europe's finest fundamental and clinical scientists in the field of infectious diseases under the PREPARE banner. The forward thinking and imaginative European Union funding Framework has made this collaborative platform a unique reality. Since its inception, the PREPARE Consortium has already addressed challenges associated with several global infectious disease threats and WHO "Public Health Emergency of International Concern" (PHEIC), such as resurgence of MERS-CoV in the Middle East in April, PHEIC declared for poliovirus in May and PHEIC declared for Ebola virus in August. PREPARE has moved swiftly to develop an "Outbreak Clinical Research Response Mode" strategy for responding to such potential threats for Europe, and has established the "Outbreak Mode Committee", a standing committee to coordinate the PREPARE responses to infectious diseases threats for the EU (see page 4 and 5). Our bold ambition is to establish an new paradigm for epidemic and pandemic clinical research so that the processes of clinical research speed up to the extent that findings are generated in real time to inform practice when it is most useful, in the midst of the pandemic, rather than once the threat has passed. Prof. Jeremy Farrar, Director of the Wellcome Trust, whose foresight helped inspire the PREPARE platform, alludes to this on page 7 of this Newsletter. The many tasks achieved by the Workpackages and their (Co-)Leaders (see page 2 and 3) are evidence of the vitality and startlingly rapid progress of this Consortium. I would like to thank the PREPARE partners, clinical networks and associated organisations who have all worked so effectively during these first months of PREPARE. I hope you will enjoy reading our first Newsletter. There is a lot more information on our website! (www.prepare-europe.eu)

PREPARE is funded by the European Commission under grant number 602525

PREPARE PROGRESS

WHERE DO WE STAND TODAY?

By Workpackage Leaders

PREPARE has received 24 million euros of funding from the European Commission's FP7 Programme (grant 602525) and will run from 1 February 2014 to 31 January 2019. The PREPARE Consortium currently consists of 21 partners, but 7 new partners will join in 2015. The PREPARE project established 5 platforms with 11 Workpackages and is affiliated with 6 clinical networks (1 Primary Care network, GRACE/TRACE; 5 Hospital Care networks, ND4BB COMBACTE, CAPNETZ, ESICM, PENTA and SERGAS). The progress made in the Workpackages since the launch of PREPARE is summarised on pages 2 and 3.

The EARL Workpackage (WP1) aims to identify bottlenecks and barriers to the rapid set up and conduct of clinical trials in Europe in response to severe infectious disease outbreaks, and provide solutions to overcome these hurdles. WP1 has already conducted a preliminary assessment and an impressive report was delivered that will be regularly updated (more on page 8).

Alistair Nichol
WP Leader

Alistair Nichol, University College Dublin

The PRIME Workpackage (WP2) is the 'clinical counterpart' of WP1 and aims to solve key clinical bottlenecks to the rapid conduct of trials. This will be achieved by mapping pan-European clinical management of severe infectious diseases and, where necessary, developing harmonised clinical case definitions, guidelines and pre-approved protocols for large multi-site clinical studies in Europe in response to severe infectious disease outbreaks. Literature reviews are ongoing and a full-time clinician will join the WP team this month to take forward the mapping of health-service utlisation, clinical managment and clinical outcomes of selected infectious disease syndromes across the PREPARE networks.

Peter Horby
WP Leader

Peter Horby, University of Oxford

The Workpackage on observational studies - PRACTICE A (WP3) aims to deliver a large-scale prospective observational study of infections with epidemic potential in Europe. The initial focus will be on four major infectious disease syndromes: acute respiratory infections, central nervous system infections, severe acute diarrhoea, and severe undifferentiated fever syndrome. The study will provide unique data on aetiologies, risk factors, disease burden, care patterns and clinical outcomes in adults and children across Europe. This study will also provide a clinical research platform for conducting rapid observational clinical studies of any emerging pathogen in hospitalised and primary care patients. Following two recent meetings between WP3 protocol team members and other WP teams (WP4/6/7) the study design is being finalised and we expect the protocol to be completed in October.

Peter Horby
WP Leader

Peter Horby, University of Oxford

The Workpackage on primary care interventions studies - PRACTICE B (WP4) aims to design and deliver the largest-ever pragmatic, publically funded randomised trial of antivirals for influenza-like-illness in primary care. The trial will generate unique, real-world evidence about whether antivirals are cost effective when used in every day clinical practice, and if so, which sub-groups are most likely to benefit. The WP team, a partnership between the Universities of Oxford and Utrecht, has designed a novel, open, adaptive trial, and the protocol is almost ready for first submission for ethics approval. The next phase will focus on training and set up of the 20 primary care research networks across the EU that will begin recruiting into the trial in the winter of 2015/16, and recruitment will continue over three consecutive flu seasons.

Chris Butler
WP Leader

Chris Butler, University of Cardiff and University of Oxford

The Workpackage on intervention studies in Intensive Care Units - PRACTICE C (WP5) aims to evaluate different treatment options for patients with community acquired pneumonia (CAP), who require invasive mechanical ventilation, and are admitted to the ICU. The ultimate goal is to build a network of approx. 100-150 ICUs in which multiple potential interventions can be tested using an adaptive response randomisation design. Currently, WP5 is planning to start winter 2014/2015 with a feasibility study to evaluate the logistics of data management, inclusion of patients, and clinical practice in 6 selected ICUs. During that time period, WP5 will finalise the protocol of the full intervention study, and is planning to start the IRB submission process in spring 2015 in the 6 selected feasibility study sites. After this, WP5 will continue to expand the number of ICUs in the study network, aiming to have the study up and running in approx. 15-20 sites in winter 2015/2016.

Marc Bonten
WP Leader

Marc Bonten, University Medical Centre Utrecht

The pathogenesis Workpackage - PATHOS (WP6) has conducted systematic reviews on several aspects concerning the pathophysiology of severe acute respiratory infections in aid of identifying priority knowledge gaps which can and should be addressed by PREPARE. Furthermore, in a multi-laboratory effort, existing platforms to assess host gene expression profiles are being validated in preparation of near future pathogenesis studies in existing and prospective patient cohorts.

Menno de Jong
WP Leader

Menno de Jong, Academic Medical Centre

The diagnostic Workpackage - PREDICT (WP7) is preparing protocols for a standardised collection and transport of specimens, and a harmonised detection of pathogens in the different clinical studies. WP7 will make an inventory in October/November 2014 of available diagnostic capacities in the collaborating diagnostic microbiology laboratories in the clinical networks and has prepared a questionnaire for this purpose.

Greet Ieven
WP Leader

Greet Ieven, University Hospital and University Antwerp

The Clinical Research Information Sharing Workpackage - CRISP (WP8) has created and launched the initial version of the public website for PREPARE (prepare-europe.eu). Other important activities were the fine tuning of the data management system RO2 in order to enable its use for all data collection processes within PREPARE. The first survey was sent out for WP1 (EARL) to several Network coordinators to get information on hurdles for research in Europe. In negotiation with the clinical workpackages all requirements to perform data management for the clinical studies were established and documented in the data management plan. On request of the PREPARE 'Outbreak Mode Committee' a survey was sent out at the end of August to PREPARE contacts in approximately 750 organisations within 40 countries to get information on healthcare preparedness for Ebola in European hospitals. More information about the survey can be found on page 5 of this newsletter.

Frank Leus
WP Leader

Frank Leus, University Medical Centre Utrecht

The Education and Training Workpackage - CREATE (WP9) completed an Educational Needs Assessment to identify the training and education requirements of all WPs and clinical networks, and better understand our educational responsibilities to external stakeholders. The results are being analysed but it looks like education requirements will fit into approximately 6 domains and cover areas as diverse as epidemiology, statistics, infection control, trial methodology, communication to the public, and lessons learnt for previous pandemics/epidemics. This platform will link with other WPs to make standard operating procedures e.g. for obtaining and transporting specimens, readily accessible.

Anita Simonds
WP Leader

In conjunction with the European Respiratory Society (ERS) we have begun construction of the PREPARE Virtual Learning Platform to disseminate knowledge and educational resources; and are now collaborating with our partner societies (ESCMID, ESICM, ESWI and WONCA) to build congress content for next year which will feed directly into curriculum development.

Anita Simonds, Royal Brompton & Harefield NHS Foundation Trust; European Respiratory Society

The Communication Workpackage - DEAN (WP10) aims to promote and exploit the PREPARE project results and associated European RTD efforts and to make research results available to the external stakeholders of the PREPARE network. Therefore, WP10 has developed a detailed communication plan outlining the target audiences, the development of tailored key messages and dissemination material. A corporate style is developed, including logos and standard templates to create and maintain a consistent and recognisable 'corporate image' of the network. A leaflet and external newsletter, using the corporate look were developed. Social Media platforms were prepared to enable external stakeholders to become aware of, learn from and implement project results. This dissemination material will be available on the new PREPARE website by the end of September.

Herman Goossens
WP Leader

Herman Goossens, University Hospital and University Antwerp

The Coordination Workpackage - COCO (WP11) aims to set up an effective management framework for the PREPARE consortium to ensure progress of the project towards its planned objectives and respect of contractual commitments. WP11 supports the different WPs on a strategic, financial and contractual level and coordinates bi-weekly meetings with all WP (Co-)Leaders to ensure continuous support and follow-up. A successful PREPARE kick-off meeting was organized 3-5 February, 2014 in Antwerp, and the 2nd annual meeting is planned 30 March – 1 April, 2015 in Venice. A PREPARE scientific advisory board (SAB) has been installed which will meet end of September.

Herman Goosens
WP Leader

Herman Goossens, University Hospital and University Antwerp

Ebola - Our greatest challenge?

Peter Horby, PREPARE WP 2 and WP 3 Leader, University of Oxford

Ebola is causing an unprecedented humanitarian crisis in West Africa, and it requires unprecedented global action. With many thousands of cases and on-going uncontrolled transmission, this outbreak shows no signs of abating. The European Commission has announced a major funding contribution and European institutions must be prepared to identify and manage small numbers of imported cases but must also contribute to the international response. It cannot be business as usual.

At time of writing over 5000 cases and 2500 deaths from Ebola Virus Disease (EVD) have been reported from this outbreak. This is more than all the previous recorded outbreaks of EVD combined and yet is widely considered to be a large under-estimate: true case numbers may be 2-4 fold higher. In the worst affected areas, Ebola Treatment Centres are overwhelmed as soon as they are opened and extreme measures to control the outbreak are being enforced, including military curfews, flight cancellations and border closures. This outbreak is unique not only in absolute and geographic scale but also in its dynamics, with ongoing and intense person to person transmission. Affecting countries where health, political and economic systems were already weak, this outbreak threatens to further destabilise them.

Europe has already received two repatriated humanitarian health workers with EVD and can expect more as the humanitarian response is scaled up. Europe must also be prepared to respond rapidly to EVD in travellers as there will be less time to arrange for reception, triage, diagnosis, isolation and care as in the case of pre-arranged repatriations. PREPARE's Outbreak Response Committee is also poised to act should an increase of EVD cases in Europe warrant a concerted clinical research response.

Whilst several therapeutic interventions have shown promise in the laboratory and in animal studies, none have been formally tested for efficacy and safety in humans with EVD. A World Health Organization expert panel recently concluded unanimously that "investigators have a moral duty to evaluate these interventions in the best possible clinical studies that can be conducted under the circumstances of the epidemic." Europe can play a role by supporting efforts to develop these products and test them in West Africa, and also by ensuring that any therapeutics used on a compassionate basis within Europe are carefully studied and the data shared immediately and openly to inform patient care and disease control in affected countries. ISARIC, the International Severe Acute Respiratory and Emerging Infection Consortium, has already responded by adapting its generic clinical characterisation protocol to capture critical data relating to viral hemorrhagic fevers.

The European Commission has announced €140M of funding to help bolster health services in Guinea, Sierra Leone, Liberia, and Nigeria. Other funders, such as the Wellcome Trust, have earmarked special funding for EVD research, including clinical trials of promising therapies and vaccines. This vital funding will enable the world's humanitarian, scientific and medical experts to respond to this crisis and ultimately enable the development of safe and effective treatments for this deadly disease.

Ebola Preparedness Survey

Menno de Jong, PREPARE Deputy Coordinator, Academic Medical Centre

In response to the current devastating Ebola epidemic in West Africa and WHO's declaration of this crisis as a Public Health Emergency of International Concern, many hospitals across Europe have taken steps to prepare for admission of patients with suspected or confirmed Ebola virus infection.

Although significant spread of Ebola virus in Europe seems unlikely at present, knowledge of the capacity and preparedness of European healthcare facilities to manage Ebola patients is essential in order to develop an appropriate and coordinated European clinical research response to improve understanding of the disease and its clinical management. As an initial step, PREPARE is therefore performing a survey which aims to provide an overview of the current state of Ebola preparedness and capacity in PREPARE affiliated hospitals in Europe. To this extent a short questionnaire has been circulated end of August to almost 1000 medical professionals in more than 750 hospitals across 40 European countries. The survey was closed on 17 September and questionnaires were successfully submitted by 242 hospitals from 38 European countries. Preliminary results suggest that the majority of surveyed hospitals would admit patients suspected of Ebola but that infrastructural and diagnostic capacities, as well as concrete preparedness activities, vary substantially. A full report of this important survey will be available in October and will help guide decisions concerning the need and prioritisation of further PREPARE activities in relation to Ebola depending on the situation in West Africa.

MERS-CoV - Remain vigilant

Marion Koopmans, PREPARE WP3 Co-Leader, Erasmus Medical Centre

In view of the substantial increase in cases of Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV) in the spring of 2014, the Outbreak Mode Committee (OMC) reviewed the situation in order to assess the possible role of PREPARE.

Since the initial detection in September 2012, more than 800 cases of MERS-CoV have been reported to the World Health Organization (WHO), with an overall case fatality rate around 30% (1). New cases continue to occur. Based on current information, the virus is able to transmit from person to person, although this seems limited to close contacts of ill persons. An estimated 75% of the notifications from the most affected region (Kingdom of Saudi Arabia; [KSA]) have been attributed to healthcare associated outbreaks, including healthcare workers and visitors. Unlike the situation during the SARS outbreak, full control of the outbreak seems unlikely in view of the finding that MERS-CoV is widespread in dromedary camels in the Arabian Peninsula, that may shed virus through nasal secretions, saliva, milk and feces (2).

While at present, MERS-CoV is not considered a pandemic threat, the continuous potential for new zoonotic introductions, coupled with severity of the disease calls for vigilance. Across Europe, a small number of MERS-CoV cases has been diagnosed, all in persons with recent travel to the Arabian Peninsula (1). Earlier studies in returning travelers who attended the Hajj in KSA showed that a high proportion of attendees develop respiratory disease during the trip, reflecting the conditions favoring transmission of pathogens (3). The OMC concluded that there are several outstanding questions that PREPARE can help address but most importantly this requires the ability to compare patients by use of a common protocol for sampling and data collection. As this is at the heart of the PREPARE project, it was decided to use MERS-CoV as an example for how to deploy this.

Questions that can be addressed and would provide relevant information even if numbers of patients remain relatively small are 1) what is the spectrum and evolution of symptoms in different patient groups (with and without comorbidities), and 2) what are the kinetics of shedding and immune response, in relation to symptoms? A draft study protocol was designed, modelled after the proposed ISARIC protocols and CRF's (https://isaric.tghn.org/protocols/). This has been shared with the team in charge of clinical studies in the PREPARE affiliated clinical networks, to prepare for local implementation.

1.ECDC. 11th Update Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV), 21 August 2014. http://www.ecdc.europa.eu/en/publications/Publications/Middle-East-respiratory-syndrome-coronavirus-Saudi%20Arabia-Qatar-Jordan-Germany-United-Kingdom.pdf

2.Haagmans et al. Middle East respiratory syndrome coronavirus in dromedary camels: an outbreak investigation. Lancet Infect Dis. 2014 Feb;14(2):140-5. doi: 10.1016/S1473-3099(13)70690-X. Epub 2013 Dec 17.

3.Benkouiten et al. Circulation of respiratory viruses among pilgrims during the 2012 Hajj pilgrimage. Clin Infect Dis. 2013 Oct;57(7):992-1000. doi: 10.1093/cid/cit446. Epub 2013 Jul 9.

Pandemic Research Preparedness in Australia

Steve Webb, University of Western Australia

In 2009, countries in the Southern hemisphere were the first to be exposed to a full winter flu season with widespread circulation of the new pandemic H1N1 strain of influenza A. As a consequence, Australia is well positioned to understand the consequences of making clinical and policy decisions in the absence of high quality scientific knowledge about a newly emerged pathogen. Australian's have first-hand experience to reinforce the vital importance of having a coordinated and planned approach to pandemic preparedness research.

Inspired by PREPARE, several activities related to pandemic preparedness research are underway in Australia. Firstly, there are plans to obtain funding in Australia to join the adaptive RCT being undertaken by PREPARE Workpackage 5. This RCT will enroll critically ill patients to one or more packages to identify optimal antimicrobial therapy, define the role of immune modulatory therapies, and identify optimal strategies for mechanical ventilation. A funding application is being prepared and will be submitted to the Australian National Health and Medical Research Council in February 2015. If successful, this application will support adding several thousand additional patients to the same trial being conducted by WP5. This will substantially enhance the statistical power of the current inter-pandemic trial but, like the European trial, it will, in the event of a pandemic, be able to adapt to switch to testing interventions that are most relevant for any form of Severe Acute Respiratory Infection (SARI) associated with a pandemic.

Secondly, the National Health and Medical Research Council is actively considering a proposal to fund a preparedness initiative that bears some similarity to PREPARE. Although it is unlikely to provide any direct funding for inter-pandemic research it is proposed to provide support for evaluation of local Ethical, Administrative, Regulatory, and Logistic (EARL) issues in much the same way as WP1 does in PREPARE. It is also planned to provide support for the development, and approval, of protocols for observational and randomised studies, that would be conducted in the event of a pandemic. Indeed, it has been proposed that these studies, and as updated from time-to-time, will form an appendix to the nation's pandemic operational plan.

The links to PREPARE have been vital to advancing the preparedness agenda in Australia and it is very much hoped that similar initiatives in other OECD countries will emerge as a consequence of the leadership shown by the European Union in supporting the PREPARE initiative.

COMPARE

A new Horizon 2020 project with close links to PREPARE

Frank Aarestrup, COMPARE coordinator, Technical University of Denmark

Human and animal health worldwide is increasingly threatened by new and re-emerging epidemics, placing a burden on health and veterinary systems, and food security.

Rapid identification of emerging and foodborne pathogens and subsequent provision of timely insights into the modes of transmission and prevention, pathogenesis, and clinical impact of such diseases is essential to reduce the impact and costs of disease outbreaks. As many emerging diseases are zoonoses, this requires inter-sectorial and international collaboration (the global 'One Health ' concept).
A potential breakthrough is offered by the revolution in genome technology, leading to increasing speed and reducing costs of sequencing (next generation sequencing, NGS). Such a single technology applicable to different disciplines (bacteriology, virology, parasitology) and domains (human, food, animal, environment) would facilitate global cross-cutting collaboration and information exchange, leading to rapid and coordinated responses to novel and known health threats as they emerge.

COMPARE (COllaborative Management Platform for detection and Analyses of (Re-) emerging and foodborne outbreaks in Europe) is a collaboration of founding members of the Global Microbial Identifier (GMI) initiative (www.globalmicrobialidentifier.org) and institutions with hands-on experience in outbreak detection and response, including several PREPARE partners. In September 2014, COMPARE was selected for negotiation for funding under Horizon 2020 and should kick-off early 2015.

COMPARE will establish a "One serves all" analytical framework and data exchange platform, that will allow real time analysis and interpretation of sequence-based pathogen data in combination with associated data (e.g. clinical, epidemiological data) in an "one health" approach.

We greatly welcome a close collaboration with PREPARE, which will facilitate and strengthen European research on threatening epidemics.

Challenge of the Next Pandemic - GloPID-R

Irene Plank, European Commission

The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) is a network of funders in the field of new and re- emerging epidemics.

GloPID-R was launched in February 2013 in Brussels with the key objective to start an effective research response within 48 hours of a significant outbreak to save lives and economies worldwide. To achieve this objective GloPID-R teams up funders round the globe investing in research related to new or re-emerging infectious diseases implementing the "One Health" approach which requires close cooperation between human and animal health actors. Joint work in 'peacetime' on regulatory, financial and administrative bottlenecks for preparedness research will prepare the ground for successful collaboration in the case of an outbreak.

The specific objectives of GloPID-R are:

- to address scientific, logistical, legal, regulatory, ethical and financial challenges to the rapid mounting of a research response;
- to establish a Strategic Agenda for research response to address the above mentioned challenges;
- to facilitate exchange of information between funders;
- to connect the existing and future research networks in this area;
- to involve developing countries in its activities.

GloPID-R will be operational in 2015 and during the next meeting on 30 September and 1 October 2014 in Montreal the crucial steps are to reach a final agreement on the governance, to start to develop the Strategic Agenda for the research response, to have a GloPID-R secretariat in place and to have a confirmation of participating funders. GloPID-R's goal is not to coordinate a public health response and it is not a new funding organisation. Funders from Australia, Brazil, Canada, China, Denmark, France, Germany, Japan, Norway, South Africa, South Korea, Spain, Sweden, Thailand, UK and USA have so far expressed interest in GloPID-R.
Once operational GloPID-R, with the help of PREPARE and other major initiatives, will use its full potential to fight global epidemics.
GloPID-R is actively looking to increase its geographical scope and warmly welcomes funding organisations interested in joining this effort to contact the GloPID-R Contact Point:

European Commission, Research & Innovation DG,
Unit E3 Fighting infectious diseases and global epidemics:
Line Matthiessen, Head of Unit - line.matthiessen@ec.europa.eu;
Cornelius Schmaltz - cornelius.schmaltz@ec.europa.eu;
Irene Plank- irene.plank@ec.europa.eu.

Wellcome Trust Director Jeremy Farrar

Professor Jeremy Farrar is Director of the Wellcome Trust, a global charitable foundation dedicated to achieving extraordinary improvements in health by supporting the brightest minds (www.wellcome.ac.uk). Before taking up this post, he spent 18 years in Ho Chi Minh City, where he runned the Wellcome-funded Oxford University Clinical Research Unit.

Throughout his years in Vietnam, Jeremy Farrar stood on the front lines battling potential human pandemics including bird flu and SARS (Severe Acute Respiratory Syndrome). With this international perspective and his hands-on experience of the deadly potential of infectious diseases, he has a clear vision about the great health challenges faced by the world in the coming decades.

Farrar believes the world should prepare to respond to any severe infectious disease outbreak. "Current mechanisms and structures around the world make it often difficult to implement clinical research in response to an emerging infectious disease, let alone conduct clinical trials of new interventions or improve the utility of existing interventions at anything like the speed that is needed. True, we have become better at identifying the start of epidemics, observing their passage, measuring their impact, charting their spread and counting the bodies. But too often we've left it at that, as if improved surveillance can do the job alone. We need research to get smarter and more nimble. The UK has moved in the right direction by introducing a single Health Research Authority and more streamlined approvals. But we also need pre-approved, harmonised, open access study protocols that can spring into action as soon as an epidemic arrives; we need more innovation in the design of research that maximises its value; we need to ensure that all research is published and disseminated immediately.

In short, we need a paradigm for clinical research that allows us to learn from public health threats as we tackle them. Without it we will continue to miss opportunities to save lives and advance medical knowledge."

EARL Update

UPDATE FROM PREPARE WORKPACKAGE 1

The EARL Team

The EARL Workpackage is led by Alistair Nichol with his team from the University College Dublin, together with a team of researchers from Cardiff University led by Chris Butler, and Steve Webb in the University of Western Australia. EARL (Ethical, Administrative, Regulatory and Logistical solutions) aims to identify and implement solutions to key structural bottlenecks and cultural and behavioural barriers to the rapid implementation of large multi-site clinical studies in Europe in response to severe Infectious Disease outbreaks.

EARL has completed an ambitious first deliverable; Task 1.1: 'Rapid Assessment' (due at month 4 of PREPARE). This was to conduct a preliminary assessment of the EARL landscape for the conduct of PREPARE's clinical studies in Europe. This task included mapping current EARL practices in Europe, and an early scoping exercise to begin to identify barriers and strategies to the rapid set up and conduct of clinical trials and observational studies in Europe.

The resulting EARL report is an early-stage rapid reference for PREPARE researchers. It is a live document that will be regularly updated throughout the lifetime of PREPARE.

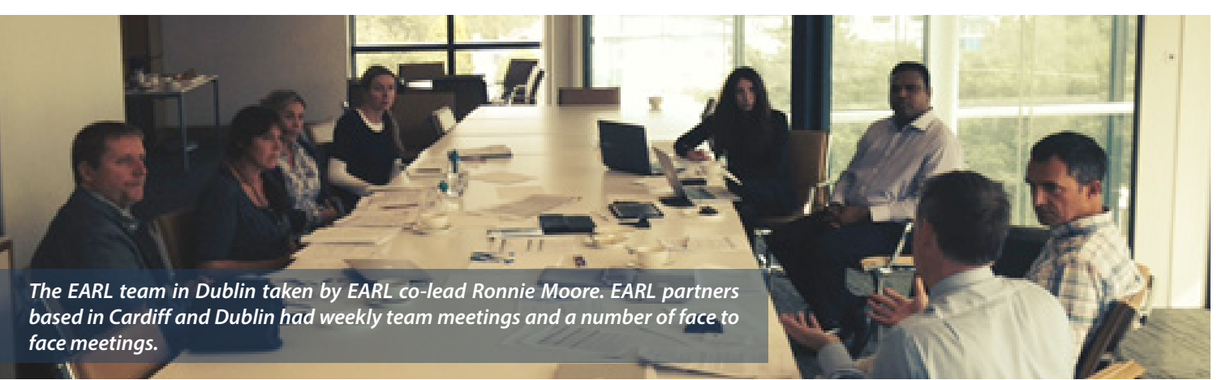
The EARL 'Rapid Assessment Report' comprised:

- information about regulatory processes summarised by European country;
- survey of the experiences of key European network and research leaders;
- qualitative semi-structured interviews with PREPARE Stakeholders.

Key Findings

- The wide variability of regulatory processes across Europe presents a challenge to the rapid set up and conduct of research studies.
- Increased and improved fast track and pre-approval processes would greatly improve feasibility. Robust and consistent information about the availability of these processes is needed.
- Clinician time pressure is perceived as a key barrier to conducting research during an epidemic or pandemic. There is a need for a harmonised approach to informed consent and participant recruitment practices.
- Socio-cultural factors play an important role in terms of risk, trust and public engagement. This is in the context of broader public misgivings about the role of science, medicine and the media and needs to be addressed from the earliest stages of clinical research.
- Other identified barriers included costs, funding, intellectual property, as well as broader contextual factors such as the role of institutions, hospitals, industry and academia as part of the political economy.

The report was presented and well received by the PREPARE WP Leaders in Amsterdam in June 2014. The report will be made available to PREPARE partners through the PREPARE website. The delivery of the EARL report emphasizes a good practice partnership between the PREPARE partners and was key to achieving this EARL deliverable. WP1 would like to acknowledge the help of PREPARE partners, associated networks and organisations who offered advice, assistance and feedback on the report, and administered the survey.



The EARL team in Dublin taken by EARL co-lead Ronnie Moore. EARL partners based in Cardiff and Dublin had weekly team meetings and a number of face to face meetings.

PREPARE NEWS

GloPID-R meeting Canada

The Canadian Institutes of Health Research (CIHR), Institute of Infection and Immunity (III) and the European Commission jointly organize the Global Research Collaboration for Infectious Diseases Preparedness (GloPID-R) meeting in Montreal from September 30 to 1 October 2014. The key objectives are to reach a final agreement on the governance of GloPID-R and to start the development of a Strategic Agenda for research response. The European Commission has invited the PREPARE Coordinator to present the PREPARE Research Outbreak Response Mode as an example of a strategy for other countries or regions in the world. This will be an exciting event and a great opportunity to discuss PREPARE activities beyond the European boundaries.

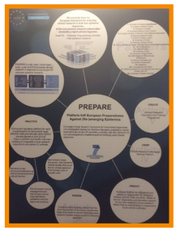
Meeting European Commission

An exceptional opportunity was given to PREPARE by an invitation to present the project at the closed meeting of the H2020 Programme Committee of the European Commission on 4 September. The deputy coordinator prof. Menno de Jong proudly gave a 20-minute presentation and received very positive feedback about PREPARE from representatives of several European or affiliated states. Besides a general interest in the development of the PREPARE clinical research network and the current activities of PREPARE, specific interest was focused on the still evolving PREPARE outbreak modes and the mechanisms by which these are triggered. Valuable input was provided by several committee members that will help to further finetune and finalise the outbreak modes and mechanisms which play such an important and central role in the aims and ambition of PREPARE.

EFIS Medal Award Winner - Peter Openshaw

The prestigious EFIS-Immunology Letters Lecture Award for an outstanding European scientist was presented to WP3 Co-Leader Peter Openshaw at the meeting of the Irish Immunology Society on the 4th of September 2014. Congratulations!

PREPARE represented at the Fifth ESWI Influenza Conference in Riga



Several partners of PREPARE attended the Fifth ESWI Influenza Conference in Riga (14-17 September), which was attended by over 700 people active in influenza research and policymaking. Menno de Jong presented current issues and new developments in clinical management of influenza, in which he also highlighted the importance of PREPARE as Europe's clinical research response network for emerging epidemics. A pandemic threats booth showcased EU funded networks active in emerging epidemics research including EMPERIE, ANTIGONE, PREDEMICS and PREPARE.

Connect

Look for more information about PREPARE's projects on our website or the different social media platforms.

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Utrecht, The Netherlands

HLA et Médecine
EISBM
Lyon, France

bioMérieux - Microbiology R&D
La balme Les Grottes, France

Royal Brompton & Harefield NHS Foundation Trust
London, United Kingdom

European Society of Intensive Care Medicine
Brussels, Belgium

Institut Pasteur
Molecular Genetics of RNA Viruses Unit
Paris, France

Universitätsklinikum Bonn
Institute of Virology
Bonn, Germany

ESCMID - European Society of Clinical microbiology and Infectious Diseases
Basel, Switzerland

Erasmus MC
Erasmus Medical Centre Utrecht
Department of Viroscience
Rotterdam, The Netherlands

University of Split
Dept. of Public health,
Croatian Centre for Global Health
Split, Croatia

Fondazione PENTA
Padova, Italy

Berry Consultants
Texas, United States

Imperial College London
Imperial College London
National Hearth and Lung Institute
Centre for Respiratory Infection
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University College Dublin
School of Medicine and Medical Science
Dublin, Ireland

University of Western Australia
School of Medicine and Pharmacology
Crawley, Australia

University of Southampton
Southampton, United Kingdom

CLINICAL NETWORKS

GRACE - Genomics to combat resistance against antibiotics in community acquired LRTI in Europe

TRACE - Translational Research on Antimicrobial resistance and Community-acquired infections in Europe

COMBACTE - Combatting Bacterial Resistance in Europe

Fondazione PENTA
Padova, Italy

CAPNETZ Stiftung
Hannover, Germany

European Society of Intensive Care Medicine
Brussels, Belgium

SERGAS - Hospital Clinico Universitario de Santiago Pediatrics Department
Santiago de Compostela, Spain

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