

# IS THERE LIFE AFTER COMBACTE?

**Much is being invested in the establishment of CLIN-Net and LAB-Net. Wouldn't it be a shame if European society ceases to benefit from this after 2021? The answer is obvious. This story is about looking at the future and a fruitful cooperation.**

"If we fail to put the infrastructure that's been built to good use, we'll have a divestment of value to answer for," according to COMBACTE managing entity, Marc Bonten. "That's why we began considering an independent post-2021 life for ourselves back in 2016. The networks have vast potential, especially if we pool our resources with another European program: PREPARE. The focus of that program is on being able to set up clinical research quickly in the event of impending epidemics." Herman Goossens is PREPARE coordinator as well as Academic Lead for LAB-Net. He is also a staunch proponent of a shared future existence. In fact, it has already been given a name: ECRAID, which stands for European Clinical Research Alliance for Infectious Diseases.

## Broad outline

The broad outline for life after 2021 calls for an active European network for clinical trials in the field of infectious diseases, built on the foundations laid by COMBACTE (>850 clinical care sites) and PREPARE (600 primary care sites). In this network, trials will be conducted continuously, allowing us to expand our experience and knowledge ever further. According to Marc Bonten, such a net-

work of academics could set up trials much more effectively and efficiently than CROs. "The access to the network is quite direct. Furthermore, academics are well aware of which site they should look to for a particular condition, for example. This allows us to shorten the preparation stage and realize the necessary inclusion with a smaller selection of hospitals. At the same time, we can significantly reduce the processing time and costs of trials as well."

## Game-changer

Herman Goossens claims that this initiative, which sounds so logical it's practically self-evident, is nothing less than a game-changer. "We have a once-in-a-lifetime opportunity to gear up the considerable public and private resources already invested in the EU. In 2018, we should start designing and subsequently building an ambitious infrastructure on tackling AMR as well as other infectious disease threats. We will never be in such a privileged and pivotal decision point in our lifetimes ever again." Such an infrastructure would be the only one of its kind in the world. It puts Europe in a position to take on a leadership role in infectious diseases' clinical research. "There is a great deal of interest, and the



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## THERE IS A GREAT DEAL OF INTEREST IN A PERMANENT EUROPEAN CLINICAL TRIAL NETWORK

### PREPARE

*PREPARE stands for Platform for European Preparedness Against (Re-)emerging Epidemics. It is a EU-funded network for harmonized large-scale clinical research studies on infectious diseases, prepared to respond rapidly to any severe ID outbreak. Currently, it takes two to three years to launch a study – about as long as an epidemic typically lasts. PREPARE is aimed at responding to an epidemic much more quickly and starting trials immediately in order to prevent fatalities. Furthermore, pandemics occur maybe once every 10 to 20 years. When they do, there must be a well-prepared, properly trained and experienced network in place to manage them immediately. That is what PREPARE is today, and what ECRAID will be after 2021.*

### ECRAID

- *Faster and easier clinical research*
- *Single-point access to a high quality, business-oriented research network*
- *Rapid access to and knowledge of well-developed clinical and laboratory sites*
- *An active network that continuously includes patients in platform trials*
- *A focus on services that alleviate the administrative, technical and organizational burden in clinical research and reduce timelines (lower costs, faster processes)*
- *Strong practice-based scientific expertise and commitment*

### WHAT'S IN IT FOR THE CLINICAL SITES?

- *Optimum training in conducting clinical trials*
- *Establishing a reputation as a top medical center*
- *Financial compensation for trials*

response from the pharmaceutical industry has been similarly positive, although risk aversion is understandably strong in that group. The current system with CROs is functional, so why take a risk? Therefore, we will need to convince pharmaceutical companies by getting the job done better, faster and cheaper.”

#### **Drawing up a business case**

An ECRAID Working Group – including representatives from both programs – has now been established to draw up and elaborate the business case further. Bonten and Goossens are keen to see this done right, and in such a way that a permanent and leading European clinical trial network will be in place from 1 January 2022. The working group is hoping to receive EU funding to develop a sustainable business model for clinical research of Infectious Diseases in Europe, built on COMBACTE and PREPARE. Clearly, the EU recognizes the potential of a shared future existence of these projects.

#### **Logic behind the collaboration**

For COMBACTE, teaming up with PREPARE is a logical step, says Herman Goossens. “Naturally, there are differences between the two worlds of infections with antibiotic-resistant bacteria and viral pandemics. With antibiotic trials, the emphasis is on completing the trial quickly, while with a viral pandemic, you need to start as soon as possible. What they have in common is a need for a network of clinical sites with thoroughly trained staff in conducting trials. A network in which you can roll out a protocol and get approval from medical committees quickly, and in which the accompanying administrative tasks can be wrapped up quickly as well. PREPARE is already collaborating with CLIN-Net and LAB-Net.

We compliment each other's set of skills and strengthen each other's networks. In the future, when we collaborate within ECRAID, we intend to round out the network of laboratories and clinical investigation sites with a European network of well-trained general practitioners. Just imagine the possibilities for research in epidemiology and infectious diseases. Yes, there is true potential in a shared future.”

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