



VIA MAIL
SITO sì
IFO sì

**Ai Presidenti degli Ordini
dei farmacisti**

**Ai Componenti
il Comitato Centrale**

Loro Sedi

Si informa che il Ministero della Salute ha comunicato che l'azienda italiana Advent IRBM di Pomezia e lo Jenner Institute della Oxford University hanno annunciato che inizieranno a fine aprile in Inghilterra i test accelerati del prototipo di vaccino anti Covid-19 su 550 volontari sani.

Il vaccino potrà essere disponibile già da settembre in modalità d'uso compassionevole per agenti delle forze dell'ordine e personale sanitario, ma sarà necessario molto più tempo perché possa essere disponibile su larga scala per la popolazione.

In proposito, l'Amministratore delegato dell'azienda di Pomezia ha dichiarato che è in fase finale una trattativa per velocizzare ulteriormente lo sviluppo e la produzione industriale del vaccino.

Il Dicastero ha, poi, precisato che sono cominciati - e hanno dato primi risultati positivi - i test preclinici di altri cinque candidati vaccini italiani condotti dall'azienda Takis. Complessivamente, sono oltre 50 i progetti allo studio nel mondo.

Si segnala, inoltre, che l'Università degli Studi di Milano e l'Asst Fatebenefratelli-Sacco hanno dato avvio alla prima 'biobanca' di Covid-19, una banca biologica con il compito di raccogliere e conservare i campioni di sangue e tessuti relativi al Sars-CoV-2. La sede fisica della Banca biologica sarà all'Ospedale Sacco e sarà gestita dai docenti e i ricercatori della Statale di Milano.

Gli elementi custoditi saranno preziosi oltre che per lo studio e lo sviluppo di strategie diagnostiche e terapeutiche, anche per la realizzazione di un vaccino.

Nella struttura verranno raccolti i campioni dell'ospedale Sacco e quelli di tutti gli ospedali che hanno già iniziato a farlo anche in altre Regioni italiane, previo consenso del loro comitato etico e dei pazienti.

Infine, si comunica che le Agenzie regolatorie internazionali hanno discusso, durante un workshop dedicato al COVID-19, le modalità con cui dati generati

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durante la pratica clinica potrebbero integrare le evidenze scaturite dagli studi clinici su potenziali trattamenti terapeutici o vaccini contro COVID-19 (cfr. all.1).

Il workshop, che si è svolto il 6 aprile sotto l'egida della International Coalition of Medicines Regulatory Authorities (ICMRA), è stato presieduto congiuntamente da Health Canada e dall'Agenzia Europea dei Medicinali.

Nel seminario è stata riconosciuta l'importanza degli studi osservazionali sui dati del mondo reale per aumentare l'efficacia e l'efficienza dei processi regolatori e del processo decisionale nelle fasi di sviluppo, autorizzazione e monitoraggio dei medicinali e dei vaccini per la prevenzione e la cura di COVID-19 e per colmare le lacune conoscitive che non possono essere superate mediante gli studi clinici.

La condivisione di protocolli e risultati è stata identificata come un elemento cruciale per un approccio di tipo globale. Si è anche discusso sull'adeguatezza delle piattaforme esistenti per poterla realizzare.

Cordiali saluti.

Roma, 20 aprile 2020

All.1



ICMRA meeting: COVID-19 Real-World Evidence and Observational studies

6 April 2020

Chairs: Marc Mes (Health Canada), Peter Arlett (European Medicines Agency)

1. Welcome

Guido Rasi (EMA) welcomed the participants and stated that in these difficult circumstances, regulators can collaborate to improve public health and make a real impact.

2. Introduction and objectives

Marc Mes introduced the objectives of the meeting:

- to update on initiated or planned observational studies to characterise COVID-19 disease, any link between clinical outcome and concomitant medication use, the safety and effectiveness of vaccines and of treatments
- to explore the possibility to establish an information exchange on research questions, protocols and results
- to explore the interest and feasibility of collaboration on specific research questions.

3. Research questions and studies planned by country / region

- Marc Mes introduced the topic and opened the floor for discussion.
- A representative of EMA explained that EMA is collecting information on observational research projects and studies planned or on-going in Europe; by 3 April, 42 observational research topics have been identified in 12 European countries and some are international studies conducted in several other countries; by 3 April, 2 studies regarding ACE inhibitors and angiotensin receptor antagonists (ARBs) have been finalised, and 8 other studies on the same substances, and on NSAIDs or on (hydroxy)chloroquine are on-going. These numbers evolve quickly. The EMA will launch a study to build and test a system for the close monitoring of the safety and effectiveness of COVID-19 vaccines when they become available; this system should be in place by December 2020. EMA is also considering creating a multinational cohort of COVID-19 patients, bringing together cohorts assembled in different European studies.
- A representative of Health Canada updated the participants on planned or on-going collaborative projects in Canada. Excellent researchers and infrastructure are being leveraged to collaborate in the priority areas of COVID-19, including patient characterisation, diagnostic testing, predicting types of treatment patients will receive, and estimating treatment safety and effectiveness. As of 31 March, the Canadian Institutes of Health Research have also funded about 25 COVID-19 observational studies including qualitative research, which focus on transmission dynamics and

therapeutic/clinical management (<https://cihr-irsc.gc.ca/e/51908.html>). Health Canada is leveraging the Drug Safety and Effectiveness Network to inform COVID-19 knowledge gaps and there is potential to leverage the Innovative Solutions Canada and the National Research Council-led mechanism to respond to the needs of health care providers.

- A representative of the Center for Drug Development and Research, US FDA, explained that FDA is exploring the use of the Sentinel and Medicare systems, and is defining priorities for the near future.
- A representative of the Danish Medicines Agency, DKMA, Denmark, informed the participants that 2 retrospective studies on the impact of NSAIDs, ACE inhibitors and ARBs on the severity of viral pneumonia are being finalised and show reassuring results. Other prospective studies are on-going. In addition, the Danish Registries of patients will be opened to research proposals from researchers from other parts of the world; research questions that may be answered in the Danish cohort should be sent to a dedicated webpage address: (<https://laegemiddelstyrelsen.dk/en/about/danish-medicines-agencys-data-analytics-center-dac/registration-analyses-of-danish-covid-19-patients/>)
- A representative of the Paul-Ehrlich Institute, Germany, informed the participants on research activities regarding antibodies from convalescent patients.
- A representative of Medicines and Healthcare products Regulatory Agency, UK, said MHRA is making the CPRD, a primary health care database covering 20% of the UK population, available to researchers. CPRD covers primary care, diagnoses, treatments and vaccines. CPRD is updated on a monthly basis and will soon get data from COVID-19 patients. They also mentioned that they will perform national vaccine vigilance with real-time monitoring using CPRD.
- A representative of MHRA, UK, presented the studies on-going in the UK. A series of studies will inform COVID-19 management, including studies on ACE inhibitors and ARBs (non-COVID and COVID-specific studies), on risk factors for COVID-19 infections and on emergent therapies for viral outbreaks and pneumonia. For transparency reasons, the study links are on the CPRD website (<https://www.cprd.com/protocol-list>).
- A representative of the Medical Products Agency, Sweden, said a national registry on hospitalised COVID-19 patients is being built in Sweden to understand the safety of therapies and follow adverse events of special interest (AESIs).

4. How to inform on questions, protocols and results

- Peter Arlett introduced the discussion and the questions to be addressed:
 - Identify ICMRA members wishing to exchange information?
 - Exchange on key studies via email?
 - Monthly call to exchange information and foster collaboration?
 - Public registration of studies: use of EU PAS Register as global COVID-19 resource?
- A representative of EMA introduced the EU PAS Register (<http://www.encepp.eu/encepp/studiesDatabase.jsp>), which is a public tool available to everyone to register studies and upload study protocols and results. Researchers are encouraged to use it to exchange information, increase collaboration for multinational studies and support use of common protocols and collection of common data elements.

- A representative of PEI, Germany, stated that exchange of information by email (with copy to those interested) would be useful; for registration of observational studies, ClinicalTrials.gov is another tool.
- A representative of MPA, Sweden, stressed the usefulness of regular monthly interactions on observational studies and research questions.
- A representative of CDER, US FDA also proposed monthly meetings with in-between inter-personal exchanges. Discussions could include logistical challenges.
- A representative of WHO stated this ICMRA initiative was excellent and emphasised that because complementary work is done at WHO level, the different initiatives should be coordinated for the benefit of the global community.
- A representative of MHRA, UK, said a central register of studies is a good aspiration, but a practical first step is to share website addresses where the studies are posted.
- A representative of the South-African Health Products Regulatory Authority, South Africa, expressed the importance of sharing information with countries who have a lower capacity to access information.
- A representative of MHRA, UK, said MHRA supports exchange of information especially between people conducting their own research and welcomed the opportunities to share protocols.
- Marc Mes and a representative of Health Canada proposed that priority areas for information should be discussed at the next monthly call, as a starting point of this collaboration and that it would be helpful if each regulator could propose specific questions for discussion.
- Peter Arlett summarised the discussion and concluded that there was agreement on the:
 - Need for a common email address (ICMRA-COVID@ema.europa.eu)
 - Monthly calls on Covid-19 observational research
 - Posting of studies in public registries (on the EU PAS Register, or national websites).

5. Identifying opportunities for collaboration on studies

- Peter Arlett introduced the topic stating that different organisations are doing research. Peter gave the examples of ACE inhibitors, ARBs, NSAIDs and research on clinical outcomes where multiple countries and research groups are addressing similar questions. Collaborations could focus on important priorities for research.
- A representative of EMA gave an example of international collaboration where a set of studies on direct oral anticoagulants, involved direct collaboration between EMA, Health Canada and the FDA.
- A representative of DKMA mentioned they were interested in collaborating on bacterial superinfections in COVID-19 infections, and the need for data on which antibiotics are effective in this situation. They raised the question of whether there were any data from France, Spain or Italy?
- A representative of the Italian Medicines Agency, AIFA, Italy, responded and said she was not aware of studies on superinfection, but with the decrease in COVID-19 cases, Italian clinical sites may now have more time to address this issue through observational studies. No clinical trial application has been submitted to AIFA on this topic.
- A representative of MPA, Sweden, presented another issue: clinical trials include patients as severely/moderately/mildly affected patients, but little is known about special populations which

may have different benefits and risks, and different concomitant medication, such as cancer patients or patients transplanted with allogenic stem cells.

- A representative of WHO will inform participants about WHO activities in writing.
- A representative of CDER, US FDA, supported the need to address populations of interest.

Conclusions

Marc Mes and Peter Arlett summarised the discussions:

- Effective collaboration between medicines regulators will have a positive impact on public health
- There is a large amount of research on ACE inhibitors and ARBs demonstrating the opportunity for coordination on research priorities and study planning
- Research questions evolve quickly with new questions requiring rapid answers
- Feasibility of mechanisms for collaborations:
 - Email exchanges on projects, logistics and other challenges encountered, protocols and results of studies
 - Monthly teleconference
 - Publication of observational studies on national websites, ClinicalTrial.org (clinical trials and observational studies) or the EU PAS Register (observational studies only)
- Research questions of interest:
 - ACE inhibitors, ARBs, and NSAIDs (noting the extensive ongoing work the focus should be on exchange of results and discussion on interpretation)
 - Superinfections
 - Benefit/risk of interventions and therapies
 - Special populations (e.g. transplant population, pregnant women and children)
 - Antivirals and Vaccines effectiveness and safety.