

Efforts on COVID19 in Europe



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Jacques Demotes (MD, PhD, MBA)氏は神経学者であり細胞生物学の教授である。Demotes氏は臨床神経内科医及び基礎神経科学者として勤務した後、ボルドーの臨床研究センター長に就任した。2004年以降、Demotes氏はECRIN(European Clinical Research Infrastructure Network: 欧州臨床試験基盤ネットワーク)の発展を牽引し、2014年には欧州各国による共同研究の支援を行う欧州の研究基盤でありパリを本拠地とするECRIN-ERIC(European Research Infrastructure Consortium: 欧州研究基盤コンソーシアム)の責任者に就任した。フランスの高等教育・研究・イノベーション省の生物医学・医療部門のアドバイザーである。OECD(Organization for Economic Cooperation and Development: 経済協力開発機構)が2012年に示した臨床試験の管理に関する勧告(OECD Council Recommendation on the Governance of Clinical Trials)案を作成したワーキンググループの議長を務めた。

Jacques Demotes, MD-PhD-MBA, is a neurologist and professor of Cell Biology. He worked as a clinical neurologist and basic neuroscientist, then as head of the clinical research centre in Bordeaux. Since 2004 he has driven the development of ECRIN and in 2014 he became Director of the Paris-based ECRIN-ERIC, the European research infrastructure supporting multinational clinical trials in Europe. Advisor for the Biology and Health research department of the French Ministry of Higher Education, Research and Innovation. Chaired the working group who drafted the 2012 OECD Council Recommendation on the Governance of Clinical Trials.

COVID19の爆発的な感染拡大により、COVID19の診断、前臨床薬又はワクチン開発及び臨床研究に関して研究プロジェクトの実施を求める多くの声が寄せられた。多数の観察及び介入試験が資金提供を受けて実施されたものの、欧州諸国間の連携が十分でなく、その結果、多くの試験は類似した研究課題に取り組み検出力不足であった。しかし、一部の大規模試験は1カ国での実施(UK RECOVERY試験)又は欧州委員会から資金提供を受けた欧州各国による共同研究(REMAP-COVID試験、EU-RESPONSEプロジェクト)としてデザインされたものであった。これらの大規模試験は複数の投与群を設定するアダプティブプラットフォーム試験であり、複数の治療薬を別の用途で使用すること又は承認申請を目的として検証することが可能であった。ワクチン開発に関して、欧州委員会はアダプティブプラットフォームとは少し異なる方法を採用し、ボランティア参加者のファイル、試験実施施設と専門の検査機関及び免疫モニタリングを行う施設で構成されるワクチン試験ネットワークの構築を進めた。このネットワークを利用する研究依頼者は試験及びデータ管理サービスも受けることができるため、試験の統一化及び相互運用性が促進される。

The COVID19 outbreak triggered multiple competitive calls for research projects on diagnostics, on preclinical drug or vaccine development, and on clinical research. Many observational and interventional studies were funded, but without enough coordination between European countries, resulting in multiple underpowered studies addressing similar research questions. However some large trials were designed either in a single country (the UK RECOVERY trial) or as multinational trials, funded by the European Commission (the REMAP-COVID trial, the EU-RESPONSE project). These large trials were designed as multi-arm adaptive platform trials, able to test multiple treatments either for repurposing or for registration. Regarding vaccine development, the European Commission adopted a slightly different approach through the establishment of a vaccine trial network composed of a volunteers' file, of investigation sites and of specialised laboratories and immuno-monitoring facilities. Sponsors using this network have also access to trial management and data management services promoting harmonisation and interoperability.

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« Global clinical research in COVID19 era »
Efforts on COVID19 in Various Countries :
France and Europe
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Clinical research on COVID19 in Europe

- ~1000 randomized trials on COVID in Europe (> 3000 worldwide)
▪ <https://covid-19.cochrane.org/>
- Duplication and fragmentation : bottom-up calls
▪ local, national competition
▪ mostly national funding
- Repurposing trials
- Registration trials
▪ marketing authorization for new medicines (monoclonal antibodies...)
- Vaccine trials

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Which priorities ?

- Bottom-up funding decision ?
- Or top-down prioritization by health authorities ?
 - to initiate trials ?
 - to terminate trials ?
- Role of health technology assessment (HTA) and preclinical expertise
- Need for pan-European coordination
 - Exchange of information on planned and ongoing trials
 - Coordinate / combine national initiatives
 - Need for pan-European trials and for multinational funding

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Major COVID19 adaptive platform trials

- Multi-arm, adaptive platform trials (ex. WHO SOLIDARITY)
 - master protocol and subsequent amendments
 - shared control arm
 - rapid patient recruitment
- Prevention, treatment, vaccine
- Pragmatic trials ? Open-label ?
- Hard primary endpoints
- Mild, moderate or severe disease
- Primary care, ward, or intensive care
- Antivirals, immunomodulators, other treatments

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Coordinating COVID research

- Coordination module between H2020 RECOVER and H2020 EU-RESPONSE
- promote coordination, share best practice, optimise use of resources
 - Trial Coordination Board (TCB):
 - Coordination of major COVID trials (REMAP-COVID, Discovery, EU-SolidAct, WHO Solidarity, Recovery, Principle, ACTIV-3)
 - Dialogue with relevant stakeholders (EMA, EUnetHTA, CTFG, ECDC, WHO etc).
 - Dialogue between DSMBs
 - Joint access advisory mechanism (JAAM):
 - Coordinated access to EU-RESPONSE and REMAP-COVID
 - Investigator-initiated or industry-initiated arms

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COVID trials : lessons learnt

- Cooperation / coordination vs. competition
 - Local, national and regional competition, bottom-up calls -> overlap
 - Top-down strategy and coordination mechanisms to avoid overlap
 - ex : urgent public health COVID studies <https://www.nihr.ac.uk/covid-studies/>
- Multinational funding
 - Central budget ? Cross-border funding ? Common pot ?
- Regulation
 - Harmonised regulation ? Risk-based oversight ?
 - Fast-track procedures
- International clinical research infrastructure

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開催にあたって

プログラム

第1部 セッション1

第1部 セッション2

第2部

第3部 セッション1

第3部 セッション2

Greetings

Program

Part 1 Session 1

Part 1 Session 2

Part 2

Part 3 Session 1

Part 3 Session 2