ICN International Clinical Trial Center Network

NEWSLETTER

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"The New Normal" after COVID-19

COVID-19 has changed the way we live our lives. At first, we were wishing the pandemic could be over soon and the world could assume normal. Two years passed by and we are still wearing masks and the scientists are striving hard to figure out how to combat the virus. The world has shifted, but it is not completely on the bad side. We just need to learn to adapt to the new normal.

Clinical Trials Centre, The University of Hong Kong

In Hong Kong, more investigators are putting their research focus on emerging infectious diseases, as they see this field's importance and rising needs. A growing trend is observed in the percentage of clinical studies in infectious diseases at our centre and we expect this trend will continue.

On the side of research ethics and regulatory guidelines, there are updates in the approval mechanisms. COVID-19 has made people realized the importance of timely review of research proposals relating to public health emergencies. Every step of the study is competing with time, so scenarios similar to COVID-19 are now taken into consideration.

Institute for Advancement of Clinical and Translational Science, Kyoto University and Kyoto University Hospital

On March 23, 2021, Ministry of Education, Culture, Sports, Science and Technology (MEXT), and Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI) released the Ethical Guidelines for Medical and Health Research Involving Human Subjects. The informed consent section of this document addresses the investigator could use electronic approach such as digital device or online to explain and obtain informed consent from the subject.

In the guidance released on April 16, 2021, the authorities extensively elaborate the investigator needs to
(1) verify if the person is the subject
(2) explain the research content, give the opportunity for the subject to ask questions, and answer questions sufficiently
(3) make sure it is easy for the subject to browse the consent items including the explanations even after the subject signs the consent, and provide the documents especially when the subject requests.

Furthermore, the guidance presents 2 e-consent examples. The digital device could be tablet for the subject to browse and sign, and the online/network could be a website link for the subject to browse and sign by clicking the consent button.

Source:
Guideline:
https://www.lifescience.mext.go.jp/files/pdf/n2262_01.pdf
Guidance:
https://www.mhlw.go.jp/content/000769921.pdf

"The New Normal" after COVID-19 (cont')

Clinical Trials Center, University of Zurich and University Hospital Zurich

There is great interest in performing clinical trials in a decentralised manner, both internationally and in Switzerland. Therefore, Swissmedic (Swiss authority for authorisation and supervision of therapeutic products) and swissethics (umbrella organisation of the Swiss cantonal Ethics Committees) published a position paper on decentralized clinical trials (DCTs) with medicinal products in 2021. Conventional clinical trials with medicinal products (IMP studies) are sometimes very time consuming for trial participants and often require a high degree of mobility since trial participants have to travel to a trial site. One objective of DCTs is to partly transfer the trial visits or assessments from the trial site to the participants's home in order to reduce the practical obstacles to trial participation and to integrate the visits more smoothly into the participant's daily routine. In the position paper, Swissmedic and swissethics are emphasizing the increasing importance of DCTs for IMP studies but also the challenges coming along with it, including legal frameworks, safety, data capture as well as electronic patient information and informed consent.

Source: Swissmedic (https://www.swissmedic.ch/swissmedic/en/home/zhumanarzneimittel/clinical-trials/clinical-trials-on-medicinal-products/publikationen.html)

Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust

In March 2020, the Covid-19 pandemic struck and all aspects of life changed including our approach to the conduct of clinical trials. Many trials were paused at this point. Research staff were re-deployed to front line clinical duties and in the interests of patient safety, efforts were made to minimise non-essential health care interactions making study visits challenging. For many studies, nearly two years on, Covid-19 continues to have a huge detrimental effect. Those studies that have re-opened continue to face the challenges of limited resource and complex logistics. Moreover, new research, even in major areas, such as cardiovascular disease or cancer, has been hindered by reductions in funding opportunities, and diversion of attention and resource to Covid-19.

However, there have been some positive impacts of Covid-19, which will shape the way we do clinical trials for years to come. In the digital era, many studies pivoted to using remote follow up – telephone or video consultations, with research staff visiting patients at home to administer trial drug or collect samples. Taking trials to the patient facilitates participation, and will hopefully increase underrepresented patient populations in trials moving forwards.

Furthermore, at a central level, there have been great strides streamlining processes. In the UK, a fast track ethical and regulatory review process was developed enabling approvals to be granted in days, rather than weeks or months. Various oversight committees were formed by the Department of Health and Social Care, which provided strategic oversight, expert opinion and most efficient use of limited resource. This led to the prioritisation of a number of platform studies including RECOVERY (treatments for hospitalised patients with Covid-19), PRINCIPLE and PANORAMIC (treatments for patients in the community with Covid-19), PROTECT_V (pre-exposure Covid-19 prophylaxis in vulnerable patients), and HEAL COVID (management of long Covid). The unified structure of the National Health Service with the embedded Clinical Research Networks have made these studies successful.

As we look to the future, conducting clinical trials in a world alongside Covid-19, let us build on these advances and efficiencies. Together, with the increased enthusiasm patients now have for clinical trials, having seen them demonstrate life-changing results in such a short period of time, Covid-19 can be the turning point to accelerate clinical trial development for many years to come.

Welcome to ICN!

Staff Update of the ICN Operations Team

Warm welcome to all new members of the ICN Operations team!

Cansu Buyukulas and Yasin Onur Polat will support the ICN Ops team from Istanbul (Istanbul University Center of Excellence for Clinical Research (IUKAMM)): They are medical doctors and residents in medical pharmacology in Istanbul Faculty of Medicine.

Joëlle Roos will support the ICN Ops team in Zurich: She is a Master's student with a background in Biomedicine and will be part of the team for 2022 while writing her thesis on the topic of General Consent.

Cansu Buyukulas

Yasin Onur Polat

Joëlle Roos

ICN Steering Board Meeting and Annual General Meeting 2021

The ICN Steering Board Meeting and Annual General Meeting 2021 was successfully held on November 16-17, 2021! Thank you for the participation of the members to make it a great success!

Launch of New ICN Website

We are pleased to announce the launch of our brand new website! New features are added, including chat forum, online membership application form, interactive timeline, etc. Come and visit us at https://www.icn-connect.org/

Global Focuses

International Guideline: GCP Renovation

Contributed by Clinical Trials Center, University of Zurich and University Hospital Zurich

Currently, in addition to the modernization of ICH-E8(R1) guideline on General Considerations for Clinical Studies, there are also the

- ICH-E9(R1) Guideline on Estimands and Sensitivity Analysis in Clinical Trials to the Guideline on Statistical Principles for Clinical Trials and the
- ICH-E6(R2) Guideline on Good Clinical Practice

under renovation. The renovation is expected to be completed by 2022.

ICH-E9(R1):
The addendum aims to improve the planning, design, analysis and interpretation of clinical trials. It contains clarifications and additions to the original ICH-E9 guideline (e.g. the intention-to-treat principle, missing data, etc.).

ICH E8 (R1):
The revision incorporates the most up-to-date concepts for achieving appropriate data quality as one of the key considerations for all clinical trials. The final document will come into force in the EU on April 14, 2022.

ICH E6(R3):
The main part of the guideline describes the 12 overarching principles in clinical trials, such as the Helsinki Declaration; rights and safety of study participants; informed consent, etc.

The guideline will be accompanied be two appendices:

- Annex 1: GCP for Interventional Clinical Trials
- Annex 2: with additional considerations for Non-traditional Interventional Clinical Trials (e.g. pragmatic clinical trials and decentralized clinical trials, trials that incorporate real world data)

China: Recent Guidance Updates of NMPA

Contributed by Shanghai Clinical Research Center

In the recent months, NMPA (China National Medical Products Administration) published some guidance about clinical trials. Some are related to centralize monitoring, statistics, randomization, and data management. Some also provide the recommendations about design of clinical trials for treating specific diseases such as pulmonary arterial hypertension, ulcerative Colitis, chronic hepatitis C. Besides, NMPA published the guidance about Pharmacovigilance, BE trials in new drugs and PK studies in different situations. The industry believe that these guidance will improve the drug development and clinical trial environment in China.

Japan: One Ethical Committee to Review Multi-institutional Joint Study

Contributed by Institute for Advancement of Clinical and Translational Science, Kyoto University and Kyoto University Hospital

The 3 government authorities (MEXT, MHLW and METI) introduced a new regulation that, as a general rule, the principal investigator should request a collective review of the multi-institutional joint study by a single ethics committee according to the Ethical Guidelines for Medical and Health Research Involving Human Subjects, released on March 23, 2021.

Source:
Guideline:
https://www.mext.go.jp/b_menu/houdou/mext_00525.html
Guidance:
https://www.mhlw.go.jp/content/000769921.pdf

Members' Snapshots

COVID-19 convalescent study

Contributed by Clinical Trial Unit, Medical University of Graz

The Medical University of Graz and its Biobank has recently published a widely noticed study about the immune response of COVID-19 convalescents (326 non hospitalized volunteers). In the framework of the ongoing pandemic, the study does not only contribute to knowledge about the disease but also highlights the importance of high quality research data that arise from patient and sample collections of biorepositories. We hope that the significance of these collections will continue to rise in the post-COVID era.

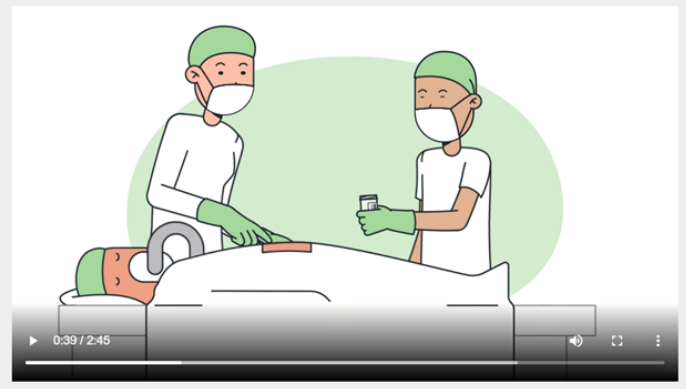
Link to the study: Long-lasting immune response to a mild course of PCR-confirmed SARS-CoV-2 infection: A cohort study - Journal of Infection (https://www.journalofinfection.com/article/S01634453(21)00419-9/fulltext#relatedArticles)

Biobanking-Info-Clip for patients

Contributed by Clinical Trial Unit, Medical University of Graz

The Medical University of Graz has published an innovative info clip (video) designed to inform patients and volunteers about what happens with their samples when they are stored in a biobank:

https://biobank.medunigraz.at/frontend/user_upload/OEs/oe-forschungsinfrastruktur/biobank/video/Biobank-PatientInnen-Infoclip-Englisch.mp4



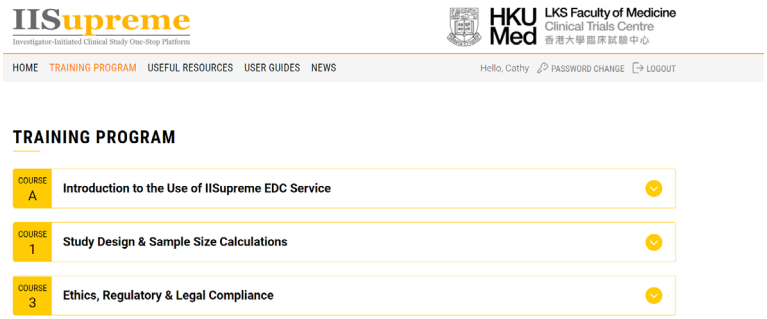
Full Launch of Investigator-Initiated Clinical Study One-Stop Platform (IISupreme)

Contributed by Clinical Trials Centre, The University of Hong Kong

IISupreme - an Investigator-Initiated Clinical Study One-Stop Platform - is launched in full! Understanding investigators' heavy and concurrent clinical, teaching and research commitments, IISupreme is launched to offer one-stop, centralized resources to facilitate the management and operations of their investigator-initiated clinical studies (IISs) in accordance with the applicable requirements.

One of the key services which is offered free-of-charge via IISupreme is electronic data capture (EDC). This service allows investigators and research personnel to collect, record and manage their clinical study data in a secure environment, and is anticipated to improve the quality and efficiency of IISs and create long-term value in terms of academic output and scientific advancement.

Another module under IISupreme is online training. Training materials and videos are made available over the platform so that users could enjoy online learning anywhere anytime.



Members' Snapshots (cont')

A successful symposium on Patient and Public Involvement in Clinical Research!

Contributed by Clinical Trials Center, University of Zurich and University Hospital Zurich

The CTC Symposium on "Patient and Public Involvement - Quo vadis?" took place in November 2021. At this event, speakers from different fields (patient organization, researcher/ physician, funding body, research infrastructure) shared their experience with PPI. In a final panel discussion, a very constructive discussion was held between the stakeholders, the participants and the CTC as host to work out which aspects should be prioritized in the field of PPI in Switzerland in 2022. In conclusion, all participants agreed on the great value and importance of PPI but also the necessity to promote PPI in clinical research in Switzerland.
The event represents the starting point for CTC's PPI platform project which will be implemented in 2022 and which will take into account the lessons learned. We will keep you up to date!