ICN International Clinical Trial Center Network

NEWSLETTER

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Challenges under COVID-19

The outbreak of COVID-19 has brought about unprecedented impact to every aspect of people's lives. In this issue of ICN newsletter, ICN members share the impacts by COVID-19 and how they tackled the challenges.

University of South Australia

The UniSA Clinical Trials Facility - like the rest of the university and its clinics – has required a flexible, contingency-based approach to COVID-19 Challenge. Adelaide (South Australia) has spent very little time in actual lockdown due to effective border closures so we have been able to operate under a risk management SCREEN – HYGIENE – MASK and DISTANCE protocol. As restrictions change (and they do often!) we can scale up or down the level of precaution. In this way, all trials have been able to continue (approx. 20) with minimal delay. Some trials have been able to alter their protocols to take advantage of telehealth facilities and remote monitoring. We suspect some of these adaptations will remain as a proven efficiency after the pandemic period.

Clinical Trial Unit, Medical University of Graz

The measures implemented by the CTU of the Medical University of Graz are in agreement with the Guidance on the Management of Clinical Trials during the COVID-19 pandemic issued by EMA on 20-Mar-2020 and the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic issued by FDA.

The goals are to:

1. keep the protection of subjects in a trial after re-start of trial performance
2. prevent informed consent withdrawal with focus on good and timely communication with subjects
3. assure the quality of the data and samples
4. restrict the impact on prolongation of timelines

- CTU daily business has been restored after the complete stop with reduced number of staff on site and alternating home-office regimen with on-call duty.
- A memo "Rules to re-start clinical trial activities" has been issued, which summarizes the measures in place to
- minimize the risk of spread of COVID-19 infection among staff and subjects. All staff members have been trained before their first activity on site.
- A risk-assessment for each single trial evaluating the re-start has been issued by CTU (focus on safety of subjects), and submitted to the IRB and HA.
- Prior to re-start of trial activities on site, a controlling meeting for the study-specific update has been performed.

Challenges under COVID-19 (cont')

Clinical Trials Center, University of Zurich and University Hospital Zurich

The COVID-19 pandemic challenged Switzerland and its health system with high numbers of hospitalized and intensive care patients over several months.

To accelerate research on COVID-19, personnel resources were reallocated, largely at the expense of other research areas which had been interrupted due to unfavorable risk-benefit ratio; and authorities applied expedite approval and review procedures. This process was driven by launching national research funds, such as a 30 million Swiss francs (approx. 32 million USD) COVID fund of the Swiss National Science Foundation.

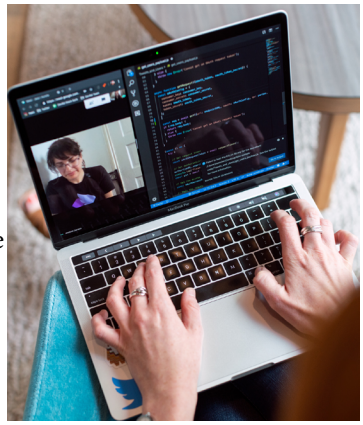
Besides speeding up COVID-19 research, collaborative effort between various disciplines was needed at hospitals. This effort paired with good communication channels and a patient-centered approach were critical to avoid competing for patients or including patients in less suitable trials.

Overall, the COVID pandemic has challenged Switzerland with shortcomings in human resources and the need to rethink and adapt research related procedures. Switzerland showed the flexibility and ability to adapt to crisis. Now it is the time to evaluate what can be learned from these experiences and to apply this development in the future.

Clinical Trials Centre, The University of Hong Kong

Hong Kong experienced a partial lockdown in 2020. In order to maintain the continuous operations, different measures were taken so COVID-19 did not pose much impact on HKU-CTC.

Flexible work arrangements were in place and rotating shifts were implemented to prevent all employees from falling ill at the same time. Operations were allowed to continue despite a reduced workforce.



Holistic IT strategies were introduced including development of electronic management platforms, remote access system, online meeting tools and enhanced IT security. These could facilitate the implementation of work-from-home arrangements.

The importance of risk management arose as one came across such challenge. The business continuity plan was enhanced to ensure our continuing operations during this rapidly changing environment.

With the effective implementation of the above measures, the number of new studies surprisingly reached an unprecedented 3-year high in 2020!

On a good side, clinical trials gained more attention and a deeper understanding by the society. It was a great chance for education so as to seek more public support.

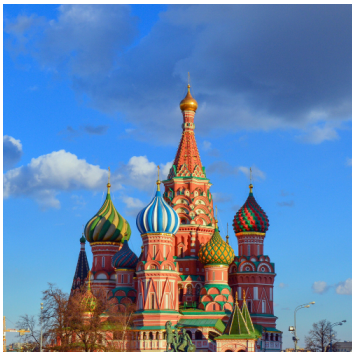
All in all, we wish the pandemic will be overcome soon by the concerted efforts of researchers and communities worldwide, while HKU-CTC will also strive towards this goal.

Welcome to ICN!

Research Institute for Healthcare Organization and Medical Management of Moscow Healthcare Department Moscow, Russia

Research Institute for Healthcare and Medical Management is one of the leading scientific organization in Moscow healthcare with qualified in-house experts on healthcare organization and medical management. The Research Institute is authorized by the Moscow Healthcare Department to promote international scientific cooperation, including membership in different organizations, associations and communities. It is responsible for conducting joint international scientific research (including preparing joint publications), developing Russian educational programs and adapting foreign ones (residency, postgraduate studies, further training, retraining), and organizing national forums, conferences, webinars etc. It also represents more than 200 Moscow medical organizations on the international scene.

Welcome to ICN as a Regular Member!



ICN Steering Board Meeting and Annual General Meeting 2021 Organized by Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust

The upcoming ICN Steering Board Meeting and Annual General Meeting 2021 will take place on November 16 & 17, 2021 in the form of virtual meeting, just as last year. It is the most important event of the year of ICN where Steering Board members will review prevailing activities and set future directions, and all members around the world will gather and share the latest update about ICN.

The meetings this year will be organized by Cambridge Clinical Trials Unit, Cambridge University Hospitals NHS Foundation Trust. The meeting schedules are as follows:-

Location	Steering Board Meeting (Nov 16, 2021)	Annual General Meeting (Nov 17, 2021)
Boston	05:00 - 07:00	05:00 - 07:30
Cambridge	10:00 - 12:00	10:00 - 12:30
Essen/Freiburg/Graz/Hannover/Ibadan/ Munich/Pecs/Rome/Stockholm/Zurich	11:00 - 13:00	11:00 - 13:30
Istanbul/Kampala	13:00 - 15:00	13:00 - 15:30
Khon Kaen	17:00 - 19:00	17:00 - 19:30
Changhua/Hong Kong/Hualien/Perth/ Shanghai/Singapore/Taichung	18:00 - 20:00	18:00 - 20:30
Kyoto	19:00 - 21:00	19:00 - 21:30
Adelaide	20:30 - 22:30	20:30 - 23:00

Save the date!

Global Focuses

European Union: Implementation of the new Medical Device Regulation in the European Union

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

The Medical Device Regulation (MDR) is a regulation of the European Union on the clinical investigation and sale of medical devices for human use. Its goal is to improve patient safety and transparency by imposing stricter rules on all parties. On 26 May 2021, it repealed Directive 93/42/EEC, which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices. The Regulation was originally planned to be fully implemented by 26 May 2020. Following the COVID-19 pandemic, the European Commission and the European Parliament decided to postpone the deadline of transition time for originally approved medical devices to meet new requirements by one year to 26 May 2021.

Changes compared to the prior regulation include reclassification of devices according to risk, contact duration and invasiveness; device scope expansion, stricter oversight of manufacturers by Notified Bodies, introduction of the "Person Responsible for Regulatory Compliance" (PRRC) and of the economic operator concept, implementation of unique device identification, Eudamed registration, and increased post-market surveillance activities.

The European Commission continues to publish useful information communicating changes to the regulatory framework in the European Union (EU). Sheets published by the Commission are available here:
https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_de

Hong Kong: New Regulation for Advanced Therapy Products

Contributed by Clinical Trials Centre, The University of Hong Kong

In Hong Kong, the Pharmacy and Poisons (Amendment) Ordinance 2020 introduces a clear regulatory framework for Advanced Therapy Products (ATPs) which cover gene therapy products, somatic cell therapy products and tissue engineered products. After the Amendment Ordinance comes into operation, ATPs will form a specific subset of pharmaceutical products under the Pharmacy and Poisons Ordinance. As such, requirements for pharmaceutical products under the ordinances will apply to ATPs. These include registration prior to marketing, obtaining prior approval for conducting clinical trials, licensing of manufacturers and distributors, and import/export control. Besides, there will be additional requirements on labelling and record keeping specific to ATPs to enhance traceability of the products.

Japan: Special Approval for Emergency to Pfizer COVID-19 Vaccine

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

The issuing authority in Japan is Pharmaceuticals and Medical Device Agency (PMDA). PMDA provides clinical trial consultation, reviews clinical trial application dossier and grant new drug/device approval.

The recent update from PMDA is the Special Approval for Emergency to Pfizer COVID-19 vaccine on Feb 14, 2021, according to the PMDA news release on Feb 16, 2021. In this news release, it is noted the Pfizer vaccines are complied with the concept of Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2 published in September 2020 by PMDA. After Special Approval for Emergency is granted, PMDA states in the news release that post-approval activities will be carried out to collect post vaccination information.

Members' Snapshots

Symposium on Patient and Public Involvement in Clinical Research

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

The Clinical Trials Center Zurich is hosting its annual symposium on November 18th, 13:00 – 17:00 (CET). Since patient and public involvement (PPI) in clinical research is currently a hot topic in Switzerland, the focus of the symposium will revolve around this subject. Talks will be held by patient representatives and PPI key players of Swiss clinical research.

Interested members are welcome to register and follow the symposium online – please be aware talks will be held in German only. More information will follow in due time on the Website of the Clinical Trials Center: https://new.usz.ch/fachbereich/clinical-trials-center/

Phase 1 clinical trial of VectorFlu™ ONE, COVID-19 nasal vaccine, has commenced

Contributed by Clinical Trials Centre, The University of Hong Kong

The phase 1 clinical trial of VectorFlu™ ONE, the world's first COVID-19 nasal vaccine developed by the research team of HKU Department of Microbiology, has commenced in March 2021 at the HKU Phase 1 Clinical Trials Centre.

VectorFlu™ ONE is the first novel vaccine that is developed by Hong Kong and goes into human trial. The vaccine technology is recognized by the China government as one of the few COVID-19 vaccine technology platforms for evaluation. This phase 1 clinical trial is supported by the Health and Medical Research Fund of Hong Kong (HMRF) and Coalition for Epidemic Preparedness Innovations (CEPI), and is managed in accordance with the highest international ethics, regulatory and industrial standards.

"Symposium on clinical trials | Regions of Germany, Austria and Switzerland" in Salzburg, Austria

Contributed by Clinical Trial Unit, Medical University of Graz

This event, originally scheduled for June 2020 and initially postponed to September 2021, was rescheduled a second time due to the COVID-19 pandemic. The symposium will now take place in Salzburg from 30 to 31 May 2022.

This will be the third edition of the three-nations congress which is held alternately in the countries of the "DACH" region (Germany, Austria, Switzerland) at two-yearly intervals, and aims at all persons working in the field of clinical research, like study co-ordinators, investigators, data managers, monitors etc.

The first edition of the symposium opened in Freiburg, Germany, in 2016, followed by Zurich, Switzerland, in 2018. Attracting more than 500 participants, respectively, these events were well received.

The third edition of the symposium will take place at the Kongresshaus in Salzburg, Austria.

Participants may choose from a range of workshops and presentations, and take the opportunity for further discussions and networking with colleagues. Furthermore various exhibitors will be presenting their services on site.

Main topics covered during the congress include recent regulatory developments in the field of research, practical implementation of Good Clinical Practice, quality management and data protection, as well as trial management on site, e.g. requirements regarding source data documentation and informed consent process.

Registration will start from mid-November 2021. Further information can be found on the congress website: https://symposium-klinische-pruefungen.com/.

Members' Snapshots (cont')

How COVID-19 convalescents support research

Contributed by Clinical Trial Unit, Medical University of Graz

COVID-19 pandemic has a global impact on social life, economics and health. Scientists in academia and industry do intense research on SARS-CoV-2, to understand host immune response, virulence and pathophysiology. In order to support scientists doing research on COVID-19, Biobank Graz in cooperation with several clinical institutes collects, processes and stores biospecimen from COVID-19 convalescents. Within the framework of a specific ethics approval, participants who recovered from SARS-CoV-2 infection, were recruited through commercials in newspapers, on social media platforms and the Med Uni Graz website. Starting in June 2020, participants were invited to five consecutive study visits, where biospecimen were collected. Furthermore, data on symptom characteristics and clinical history were collected via a questionnaire.

This study is a perfect example of civic engagement during this ongoing pandemic. More than 300 volunteers consented (broad informed consent) to donate samples and data to research, which shows that people are highly motivated to support research. In return and upon request Biobank Graz informs participants about their antibody levels. In addition, ongoing research projects that access samples and/or data of the COVID-19 Convalescent Cohort are listed on the website (https://biobank.medunigraz.at/en/for-patients).

The need for samples from COVID-19 convalescents is tremendous, as they are key resources to find new and optimized treatments of COVID-19 cases, to develop novel medicine and further diagnostic tests, or improve already existing ones. Providing samples of high quality and associated data is of major importance in order to guarantee the reproducibility of research findings. All collected samples meet CEN/TS 16495:2016 requirements. In this respect, all relevant pre-analytic parameters (e.g. time stamps, temperatures, etc.) during sample collection, processing, handling and storage are documented. These parameters are critical in order to evaluate if samples are fit for a specifc experimental purpose. Biobank Graz supports researchers and study participants as a trusted partner throughout the whole biobanking process from study design and sample collection to access, thereby contributing to the discovery of novel treatments and prevention methods for COVID-19.