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Artificial Intelligence in Clinical Research

Artificial Intelligence (AI) is the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages. AI holds the great promise to solve many key clinical trial challenges. The technologies of AI have the potential to help improve the efficiency, quality and patient-centeredness of clinical trials. AI leverages computers and other machines to mimic the problem-solving and decision-making capabilities of the human mind.

Clinical Trials Center, University of Zurich and University Hospital Zurich

An artificial intelligence model assisting rheumatologists in screening for capillaroscopy changes in systemic sclerosis

by Michael Krauthammer, Director CCCZ Bioinformatics Comprehensive Cancer Center Zürich;
Managing Director Medical Informatic, Biomedical Informatics; University Hospital Zurich



Vascular changes are an important indicator for disease progression in systemic sclerosis (SSc). Nailfold capillaroscopy (NFC) is a non-invasive but time-consuming examination for assessing capillary health in SSc. In a joint work with the University Hospital of Zurich and Universities of Zurich and Bern, they thought to automate the procedure using artificial intelligence. They used routine data from the University Hospital Zurich (NFC images, clinical reports) and 'off-the-shelf' artificial intelligence models (ViT) to train an automated image classification algorithm.

The published results indicate that the AI algorithm performs at an accuracy level matching human NFC image classification performance^[1]. As such, they believe that the technology could find broad adoption, particularly in training junior rheumatologists, but also to support experts in maintaining high quality and standardized reporting, for example as part of clinical studies involving NFC examinations. In an editorial^[2], Maurizio Cutolo, Emanuele Gotelli and Vanessa Smith conclude, "the ViT is welcome and seems to represent a further valid system for an early and fast reading of the NFC images/morphological biomarkers in SSc, reaching for the first time the fusion of EULAR-validated algorithms for the delineation of the scleroderma pattern from the non-scleroderma pattern and artificial intelligence."

[1] Alexandru Garaiman, Farhad Nooralahzadeh, Carina Mihai, Nicolas Perez Gonzalez, Nikitas Gkikopoulos, Mike Oliver Becker, Oliver Distler, Michael Krauthammer, Britta Maurer, Vision transformer assisting rheumatologists in screening for capillaroscopy changes in systemic sclerosis: an artificial intelligence model, *Rheumatology*, 2022;, keac541, <https://doi.org/10.1093/rheumatology/keac541>

[2] Maurizio Cutolo, Emanuele Gotelli, Vanessa Smith, Reading nailfold capillaroscopic images in systemic sclerosis: manual and/or automated detection?, *Rheumatology*, 2022;, keac630, <https://doi.org/10.1093/rheumatology/keac630>

Artificial Intelligence in Clinical Research (cont')

Clinical Trial Center, Research and Innovation Department,
Azienda Ospedaliera SS Antonio e Biagio e Cesare Arrigo

Machine Learning approach to predict the severity of COVID-19

They explored whether explainable Artificial Intelligence methods may support medical management to predict the death risk in hospitalized patients with SARS-CoV-2 diagnosis, based on admission data.

In a observational study they collected data of 824 COVID-19 patients older than 18 years admitted to the Azienda Ospedaliera "SS Antonio e Biagio e Cesare Arrigo", from February, 24 2020 to May, 31 2021, that completed the disease treatment inside the hospital. Patients' data were collected from the electronic medical records system and paper based medical records, using REDCap® application. The dataset was used to train and to evaluate 19 predictive machine learning (ML) models (unsupervised and supervised) described by 43 features. JRIP had the best performance in 10-fold cross validation, and the best average performance in a further validation test using a different patient dataset from the beginning of the third COVID-19 wave.



The ML supervised models correctly discerned between low-risk and high-risk patients and furthermore demonstrated to reasonably perform on the third wave. Overall, these models evaluated good predictions despite the possible differences in care protocols and the possible influence of viral variants (i.e. delta variant) and used to optimize the management of healthcare path at the admission time.

(Details: <https://pubmed.ncbi.nlm.nih.gov/36578017/>)

Global Focuses

China: Implementation Rules for the Regulations on the Management of Human Genetic Resources

Contributed by Shanghai Clinical Research Institute

In 2022, China's newly added laws and regulations related to clinical trials include the "Implementation Rules for the Regulations on the Management of Human Genetic Resources" issued by MOST, which respond to some hot spots and difficulties in the industry in recent years. The relevant administrative procedures have been optimized, so that relevant investigator or company representatives can accurately prepare relevant materials according to their own conditions and submit applications in a timely manner when applying for administrative licenses or filings. In addition, the CDE also issued the "Guiding Principles for the Design and Program Framework of Drug Real-World Research".



Updates of ICN

Message from Christiane Blankenstein, ICN Chairperson 2023-2025



I am honored to serve as chair of the International Clinical Trial Center Network.

Embracing the rapidly evolving medical and clinical medicine landscape with novel approaches incorporating digital tools and data, IITs play an important role in translating medical discoveries and hypotheses into clinical research and improved healthcare. My vision is to strengthen ICN's outreach and impact by further advancing our mission to build and expand a unique and open ecosystem for creating and sharing innovative ideas to promote clinical research.

Throughout the years ICN has established a strong and visible international network built on solid standards and collaboration, complemented by multinational clinical studies, publications and workgroup outputs. The availability of a highly skilled and qualified staff within our network promotes creation of value and dissemination of knowledge benefitting its member organizations as well as supporting partners and aspiring organizations.

Individually and collectively the members from different domains with a global perspective strengthen ICN's position as one of the leading international academic clinical research networks. We are open for new initiatives, welcome fresh ideas and contributions to our ongoing endeavors striving to enhance and drive our network and its outreach.

With busy times and challenges in clinics and clinical research, as well as restrictions preventing us to see each other during the pandemic, we are looking forward very much to a lively and fruitful face to face annual meeting later this year!

Succeeding Mr. Henry Yau and sharing his "together we unite, together we share, together we grow", I want to express my gratitude and appreciation to him for his extraordinary engagement and conceptual lead and extend my thanks to our excellent Operations Team, our vice chair Dr. Tsutomu Nishimura and our members for their valuable input and much appreciated commitment.

Message from Tsutomu Nishimura, ICN Vice-chairperson 2023-2025



Under the leadership of ICN chairpersons, ICN has become an important organization in clinical research community. ICN's influence will be strengthened in the coming years for Christiane's visionary plan as chairperson. It is truly a great honor to serve as vice chairperson and participate more in ICN activities and operations.

The academic or investigator-initiated clinical trials (IITs) play an important role in new drug/device development. However investigators encounter hurdles when they carry out trials especially international investigator-initiated clinical trials. In Europe, the infrastructure is established to facilitate the IITs. This experience/information may be exchanged within ICN so investigators may learn and obtain more insights in successfully conducting international clinical trials. By making IIT friendly in clinical research, the innovations from investigators could benefit more patients.

Lastly, look forward to inviting you all to visit Kyoto Japan in the future!

Updates of ICN (cont')

Message from Henry Yau, ICN Chairperson 2021-2022 / ICN Vice-chairperson 2019-2020



Thriving Through the Pandemic

70 years before, the structure of DNA was first discovered and publicly revealed, opened the door to contemporary biotechnology research and unprecedented biomedical advancement. Medical scientists started to combat diseases and medical conditions – whether cancers, immunological disorders, infectious diseases or otherwise – at the genetic level and made countless breakthroughs in diagnoses, prophylaxes and therapies over the subsequent decades. The emergence of COVID-19, however, reminded us that the outcomes of our long-term battles with human health challenges are still far from satisfactory. We must keep fighting – by joining forces with partners sharing the same mission and vision. This was also the primary drive for the establishment of ICN in 2015.

Thanks for the trust of the ICN members, I had the honour to assume the role of vice chairperson since late-2019 – just shortly before the first discovery of SARS-CoV-2 virus – and went through my terms of vice chairperson and chairperson throughout the 3-year pandemic. That was an unprecedented experience to me.

In spite of the unforeseeably challenging environment, ICN members managed to jointly create good value by applying the strategy of GEHI (Global, Excellence, Harmonization, Impacts). ICN is a real global family now consisting of 25 members across five continents, and is connecting with research communities worldwide via a revamped website, social media page and biannual newsletters coordinated by the Communications Workgroup. We continued to engage in exchanging research excellence through annual meetings hosted by our members from Hong Kong (2020), Cambridge (2021) and Munich (2022) and symposia organized by the Data Workgroup – though they were moved on to the cyberspace during the pandemic. The Standards Workgroup and Informed Consent Workgroup initiated surveys on CTC/CTU services and informed/general consent, which are anticipated to come up with interesting results valuable to the international clinical research communities. A joint publication on how COVID-19 changed clinical research strategies was issued, and more manuscripts for publication will follow. The pandemic may have caused much changes to the world, but it has not changed our members' passion and commitment to improving the health and well-being of mankind through an evidence-based approach. ICN continues to thrive!

I would like to express my sincere appreciation for the great support by my partner vice chairperson – Dr Christiane Blankenstein, the Steering Board and the Operations Team during the period. Under the leadership of Dr Blankenstein and Dr Tsutomu Nishimura, our new chairperson and vice chairperson, ICN will undoubtedly go from strength to strength and create greater value to clinical research and human healthcare advancement.

Members' Snapshots

The role of Academic Research Organization in Clinical Research Ecosystem Symposium

Contributed by Istanbul University Center of Excellence for Clinical Research

On December 14th, 2022, a symposium entitled “The Role of Academic Research Organization in Clinical Research Ecosystem” was held in Istanbul Medical Faculty, moderated by Prof. Yagiz URESIN, with support of the Vice Rector of Istanbul University and the Dean of Istanbul Faculty of Medicine/IUKAMM director, with participation of the Vice Dean of Istanbul Faculty of Medicine, representatives from Turkish Medicines and Medical Devices Agency, Director of Istanbul University Institute of Health Sciences, Secretary General of Association of Research-Based Pharmaceutical Companies, high level academicians from other universities, and other speakers with various backgrounds within the “ecosystem”. Pre-recorded videos from ICN members were displayed. The symposium was held in 3 sessions: Experience Sharing by Senior Researchers, Center Administration and Phase I Studies and Special Topics in Clinical Research.



Contributions of the ICN were very much appreciated. Given the popularity of the symposium and the topic among the “ecosystem” we planned a clinical research workshop entitled “CTU focused solutions” on February 22nd, as a following event.

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P.S.: 60th year booklet idea is pending.

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