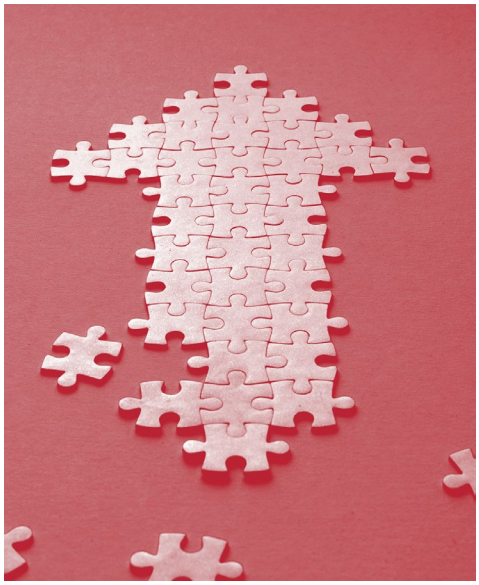
EDITORIAL



DECENTRALISED AND COMPLEX CLINICAL TRIALS: SHAPING THE FUTURE OF CLINICAL RESEARCH

We are pleased to present the ninth issue of *Regulatory Affairs Watch* on innovative developments in clinical research, namely decentralised trial approaches and complex clinical trial designs.

Technological advances over the last few decades have opened up new possibilities for using innovative elements and designs in clinical trials. But it was the COVID-19 pandemic that really pushed their use in clinical research forward. When the pandemic imposed restrictions on travel and in-person interactions, decentralised solutions made it possible to conduct certain aspects of clinical trials remotely with the help of telemedicine, digital data collection, remote monitoring, and many other technologies. At the same time, complex trials with adaptive designs and master protocols accelerated the testing of COVID-19 treatments and vaccines, allowing researchers to modify ongoing trials based on real-time data.

Decentralised clinical trials (**DCTs**) and complex trials are now being adopted across many therapeutic areas due to their patient-centric focus and research efficiency, and they will certainly play an increasingly important role in clinical research in the future. Challenges, however, remain. DCTs face issues related to data security, the validation of digital tools (e.g. wearables), the digital divide, and the need for consistent regulatory standards across regions. And complex trials, while efficient, require advanced statistical expertise and careful coordination, making them resource intensive.

This issue of *RA Watch* includes a range of articles and viewpoints on these promising – and challenging – developments in clinical trial approaches and designs.

- **DEEP DIVE:** In our Deep Dive article, our new *RA Watch* project lead and editor Güliz Vanli Jaccard looks into how design innovation has transformed clinical research by providing new operational approaches, such as those applied in decentralised clinical trials, and new methodologies, such as those used in complex trials. She considers the advantages and disadvantages of using decentralised procedures in clinical trials and outlines key global regulatory advances. In addition, she delves into complex clinical trials, such as adaptive and platform trials, and explains how they are transforming the clinical trial landscape by offering more efficient and responsive methods for testing new treatments.

- **FEEDBACK FROM:** The current regulatory framework already regulates many aspects of DCTs with medicinal products in Switzerland. However, since these types of trials are relatively new, they pose challenges to various stakeholders. In our Feedback From section, Swissmedic looks at some of the challenges – and opportunities – DCTs bring with them. In addition, Swissmedic invites

stakeholders to liaise closely with regulatory authorities and to engage in the current dialogue. Having a variety of perspectives can better equip stakeholders to find solutions to DCT challenges and take advantage of their opportunities.

- **VIEWS AND OPINIONS:** For our Views and Opinions section, the *RA Watch*'s editorial team gathered multiple perspectives on decentralised and complex trials.

  Ethics perspective: What are the ethical considerations of remote informed consent in DCTs? In our first Views and Opinions article, ethicist Brenda Bogaert explores both the challenges and opportunities of remote informed consent for research participants. She also provides some approaches for mitigating related ethical problems.

  Industry perspective: Study sponsors must weigh many factors when considering using decentralised elements in their clinical studies. In our second Views and Opinions article, industry representatives from Roche and Takeda discuss different sponsor considerations for incorporating decentralised elements in trials. They also tackle the question of why decentralised elements are not yet routinely included in clinical trials despite their many promising benefits.

  Legal perspective: Digital health technologies (**DHTs**) have tremendous potential to bring innovation to clinical research processes and research participants. Yet a lack of harmonisation in privacy laws and guidance as well as the extra level of complexity DHTs add to trials can hinder research. In our third Views and Opinions article, legal expert Gabriel Avigdor looks at some of the legal, ethical, and practical challenges of using DHTs in clinical research.

  Patient advocacy perspective: A major benefit of decentralised clinical trials is their potential to make trials more flexible, personalised, and convenient for participants. In our fourth Views and Opinions article, Nicole Gusset, who advocates for people with spinal muscular atrophy (**SMA**) at the patient organisations SMA Schweiz and SMA Europe, discusses how innovative trial designs can directly benefit patients. She also highlights their enormous potential to further advance medicines for the good of patient communities, especially in the area of rare diseases.

- **CASE STUDY:** Although randomised clinical trials are considered the gold standard in clinical research, they often face challenges such as high cost, slow recruitment, and a limited generalisability of results. The authors of our Case Study are using the novel TwiCs (trials within cohorts) design in the Swiss HIV Cohort Study to overcome some of these challenges. In their article, they discuss why and how the TwiCs approach is implemented while also considering some of the design's limitations and several mitigation strategies.

This latest issue of *RA Watch* also gives us the opportunity to introduce Güliz Vanli Jaccard, our new SCTO Regulatory Affairs Platform coordinator and *RA Watch* project lead and editor, who joined the team at the Clinical Research Centre (**CRC**) Lausanne almost a year ago. With an academic background in molecular biology and experience in research and regulatory science, Güliz has acquired expertise in multiple aspects of clinical trials and regulatory processes. We greatly appreciate her leadership on this issue of *RA Watch* and look forward to future *RA Watch* issues with her at the helm! We must admit that after more than two years of searching for a permanent RA Platform coordinator and *RA Watch* project lead, we are especially grateful to have found this rare pearl. We warmly welcome Güliz to the *RA Watch*'s editorial team, to the RA Platform, and to the CRC Lausanne!

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