

# Clinical trials



## Unsung heroes: The medical writer's role in clinical trials

**E**very year, the number of clinical trials conducted globally is increasing rapidly (approximately 10,000 annually!). According to the WHO data statistics and analysis, the number of clinical trials conducted from 1999 to 2021 has accumulated to 671,228 clinical trials.<sup>1</sup> As of February 28, 2023, 443,624 clinical trials have been registered on ClinicalTrials.gov.

The medical writer is heavily involved in clinical trials from A to Z and even beyond. Although we are not in the frontline, our role

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is nevertheless crucial as we develop most of the documents needed for trial start up, conduct, close out, and reporting (see Fig 1). This issue of *Medical Writing* is dedicated to the unsung heroes and heroines of clinical trials, medical writing professionals and scientists who help make clinical trials happen without visiting a clinic or interacting with a single patient.

This issue starts off with a foreword from the European Medicines Agency (EMA) wherein **Morgane Colin de Verdiere** and

**Catriona Ester** of the EMA Medical and Health Information Service give an overview of the implementation of EU Clinical Trials Regulation 536/2014 (EU CTR) and the launch of the Clinical Trial Information System (CTIS).

Clinical trials start with the study protocol and the medical writer is a key stakeholder in its development. Decentralised trials (DCT) came to the forefront during the pandemic. **Jonathan Mackinnon** describes tools and strategies for DCT protocols. **Kishor Patil, Chandra Kumar,** and **Siu-Long Yao** provide practical tips on the peer review process of protocols.

Once the protocol is written, reviewed, and finalised, a clinical trial application (CTA) can be submitted. As of Jan 31, 2023, CTAs are centrally submitted through the CTIS. **Ivana Turek** gives us a short overview of the differences in CTA requirements between the old (Clinical Trial Directive) and the new (EU CTR) legislations.

Before study start, protocols are registered in a clinical trial registry and details are made available to the public. Under the EU CTR, a protocol synopsis for the lay person is recommended. **Lisa Chamberlain James** looks at this new requirement and points out the challenges and opportunities.

Titles of clinical trials, too, should be understandable to the lay audience. **Leonie Leithold, Clive Brown, Julia A. Hild,** and **Thomas Schindler** performed a systematic analysis of the titles of clinical trials and identified opportunities for improvement.

Clinical trials revolve around the common theme of evaluating the efficacy and safety of medical therapies but they may differ depending on disease, patient population, and geography.

**Zuo Yen Lee** walks us through the complexity of oncology trials while **Sarah Milner, Andrew Kusmierczyk,** and **Julie Taccoen** take on the clinical trial landscape of rare diseases.

In the area of medical devices, trials are called clinical investigations, described by **Beatrix Doerr, Shirin Khalili,** and **Joan D'souza.**

And while most of us are familiar with clinical trials in the European Union, it is interesting to hear from **Eugenia Radkova** and **Irina Petrova** about similar rules and requirements of conducting clinical trials in the Eurasian Economic Union.

When the clinical trial closes, a new set of tasks awaits the medical writer. The clinical study report presents the results of clinical trials. **Surayya Taranum** provides a snapshot of the medical writer's role in the development of this milestone document.



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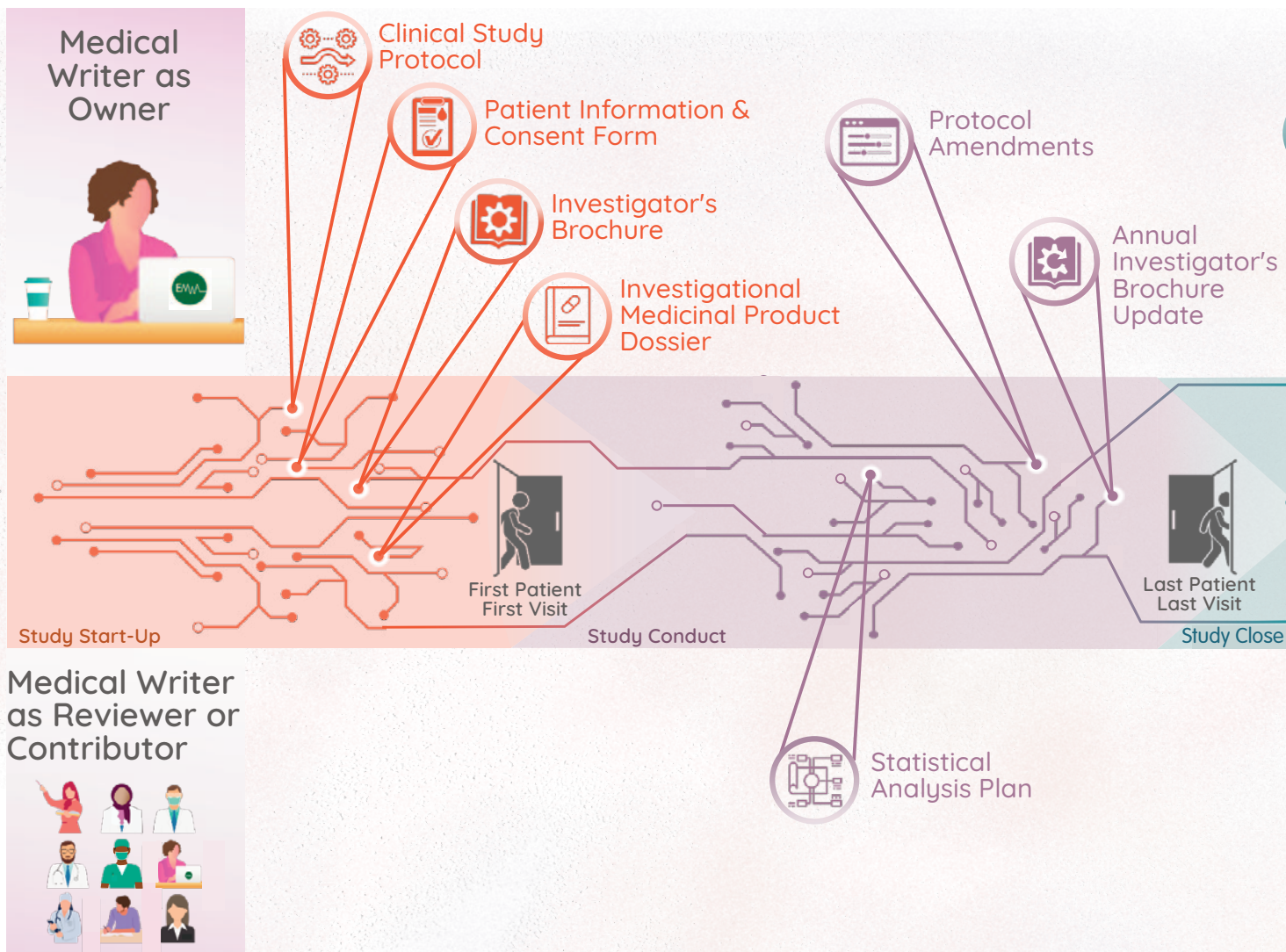
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**Figure 1**

Public disclosure of clinical trial results comes with responsibility to protect personal data. **Tatiana Revenco and Gregory Collet** address the role of medical writers as data processors in protecting patient privacy under

the purview of the EU General Data Protection Regulation.

**Ambika Subramanian** reminds us that medical writers should have a wider perspective when preparing clinical documentation as every

document is interconnected, across the different stages of a medicine's lifecycle.

Hope you find this issue as informative as we do!

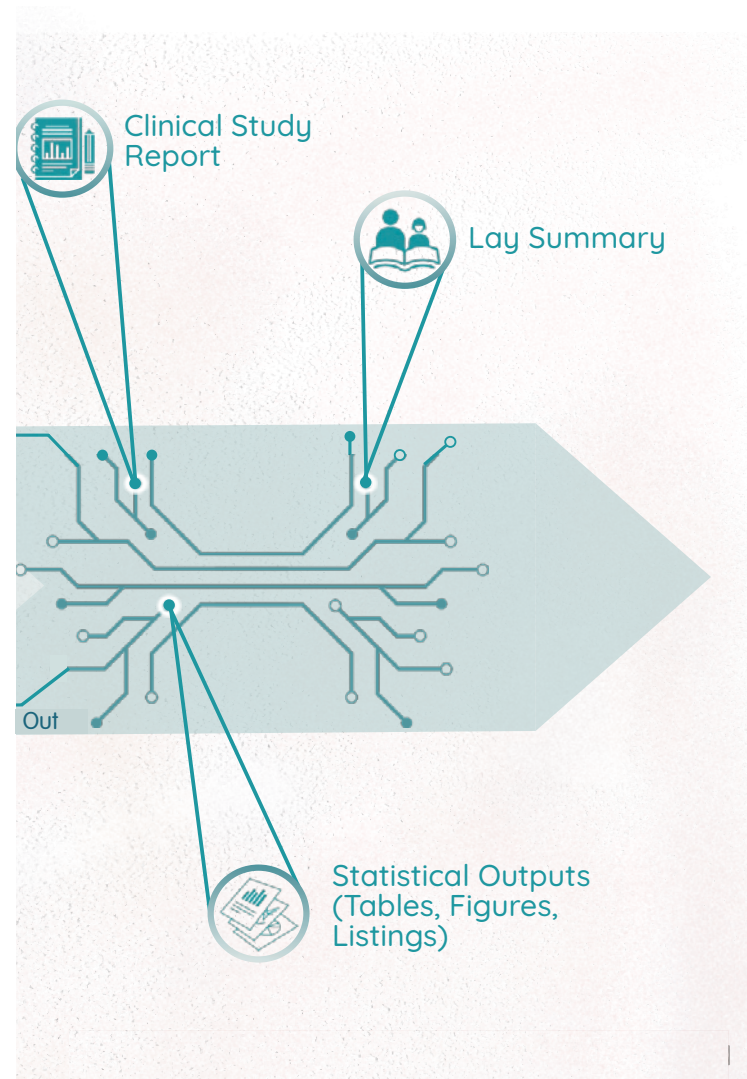
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