Complex Innovative Trials: New guideline adoption could get medicines to patients faster

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Complex Innovative Design (CID) trials could be transformed for the better, following the publication of recommendations, published today in

the *British Journal of Cancer* (Monday).

The authors believe, if implemented, the ten recommendations they've developed for CID trials could ultimately reduce the time it takes to get innovative treatments to patients with cancer.

They are now calling on clinicians, funders, regulators and the pharmaceutical industry to get behind the recommendations and work together to rapidly implement them.

CID trials are increasingly being used as an evaluation method by researchers, instead of traditional drug development pathways involving clinical trials from phases 1 to 4.

The CID approach enables researchers to carry out more complex trials that address multiple clinical questions at once. For example, a drug can be simultaneously evaluated for safety and efficacy with different cancer types, which can change as the trial progresses, accelerating the traditional route to drug licencing.

However, they can be challenging to conduct and there are currently no practical guidelines for teams that fund, design and conduct these trials in Europe.

The Experimental Cancer Medicine Centre (ECMC) network, funded by Cancer Research UK, the National Institute for Health Research (NIHR) and the health departments in Scotland, Wales and Northern Ireland, convened a working group of academics, funders, regulators, pharmaceutical industry representatives and patients to address this challenge.

They developed ten key recommendations to cover each stage of the clinical trial pathway.

Each recommendation covers a specific stage of the clinical trial pathway including: trial planning and design, protocol development, patients and public involvement, patient-facing documentation, statistical analysis, defining leadership and oversight, dissemination of results, staff training, the approval process, funding, and evaluating the impact on public health.

Taken together, these recommendations could improve the conduct, quality and acceptability of oncology CID trials in clinical research. Furthermore, improving how different stakeholders interact, promote and share their learnings from CID studies, say the authors, will foster a clinical research environment that could enable CID trials to be carried out in a range of new clinical areas.

Professor Pam Kearns, director of the Cancer Research UK clinical trials unit at the University of Birmingham and co-author of the paper, said: "We owe it to our patients to bring potentially more effective novel treatments into the clinic as quickly as possible, and these recommendations will ensure we have good quality CID trials in place to deliver this promise."

Dr. Aoife Regan, head of the ECMC programme office, said: "These recommendations show the power of the ECMC network as a convening force to help strengthen the position of the UK as a world leader in experimental cancer medicine. We hope these recommendations will have an impact not just for cancer research but for all complex trials across all disease types."

Nick Lemoine, Medical Director at the NIHR, said: "Getting promising new cancer treatments to patients who need them the most can take some time, so speeding up this process through Complex Innovative Design trials is a priority. With the expertise within the ECMC network and the new guidelines in place, the UK is now one of the best equipped

countries to deliver these trials, which represent the future for evaluating new cancer drugs."

Debbie Keatley, a patient representative and co-author of the guidelines, said: "Patients tell us that they need information about trials in an easy to understand format and language. They also want reassurance that the results seen in the trials will be applicable to real patients seen in the clinic. We welcome these guidelines, which put the patient first."

More information: *British Journal of Cancer* (2020). DOI: 10.1038/s41416-019-0653-9

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