

# SPARK EUROPE WEBINAR SERIES 2023

Wednesdays  
at 4 pm CET

SPARK Europe  
Education

## New clinical trials regulation targeted for early phase trials

Lenka Součková & Radka Obermannová

7th June 2023 | 4 – 5 pm (CET) | Online Webinar

The new Clinical Trials Regulation was implemented on January 31st 2023. What changes has the regulation brought, and which are related to the early-phase trials? Each application for a clinical trial with medicinal products in humans has to be applied through a new Clinical Trial Information System (CTIS). The first experience will be presented. What are the pitfalls of transferring research to the clinical evaluation phase?



### Lenka Součková, Pharm.D., Ph.D.

Lenka is a European Correspondent for the Czech Republic of ECRIN (European Clinical Research Infrastructure Network). She also represents CZECRIN National Network at the Clinical Trial Unit of St. Anne's University Hospital in Brno, CZ. She is a researcher at the Department of Pharmacology, Faculty of Medicine, Masaryk University with a specific interest in academic clinical trial methodology, medical writing, and regulatory issues.



### Radka Obermannová, M.D., Ph.D.

Radka is a clinical oncologist at the Department of Complex Oncological Care at the Faculty of Medicine, Masaryk University and Masaryk Memorial Cancer Institute in Brno, CZ. She is the head of the Early Phase Trials Unit, the principal investigator in many clinical trials, the author of the national guidelines for treating oesophagogastric cancer, and co-author of the European ESMO guidelines for oesophageal cancer.

### Online via MS Teams | Please register [here!](#)

Registration to the webinar is required in advance in order to receive MS Teams meeting link. The event is hosted by SPARK at the Faculty of Medicine, Masaryk University, Brno, Czech Republic

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