

Building key competencies clinical trialists of the future: CONSCIOUS curriculum projects

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Investigator-initiated clinical trials (IIT) are a broadly interprofessional field that is becoming increasingly relevant to biomedical postgraduate students, especially to validate their research question in clinical practice. Indeed, IIT represent a way to develop individualized treatment and obtain objective evidence to answer questions of day-to-day practice. On the other hand, IIT place greater demands on investigators as they extend their position to include the coordination and management role of the sponsor. At the same time, little formal training in clinical trials is available across European countries in both undergraduate and postgraduate education, and the understanding of biomedical graduates in clinical research organization may not be optimal.

A consortium of six European universities was established to fill this gap by preparing a highly practice-based and -oriented curriculum within two consequent projects – CONSCIOUS and CONSCIOUS II. Especially the CONSCIOUS II is focused on postgraduate students and provides them with e-learning lessons of practical guidance on how to design a research question and a clinical trial, the regulatory requirements that need to be met, how to conduct the trial, what activities can be delegated, and how to analyze the results. The second part targets transdisciplinary skills such as leadership, publishing, and teaching. The CONSCIOUS II pedagogical approach moves on to contextualized, case-based exercises allowing to test the acquired skills in simulated situations.

Both CONSCIOUS projects thus offer a comprehensive, free-of-charge curriculum for biomedical students but will also open a pilot course with international participation as a further extension of this curriculum.

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