



ACT-EU MSP – AG, Meeting 18th September Training

Training

- A well-trained clinical research professional is a major factor to successfully design and conduct complex clinical research
- Increase in the number of clinical trials is in contrast with the **increasing staff shortage in academia**: not enough CRA, study coordinators or investigators to properly conduct clinical studies
 - Need to attract and retain experienced staff
 - Professional pathways for staff (CRA, nurse, study coordinators, ...) that support the activities required for operationalizing and managing clinical research studies should be better defined
- **Training** contributes to strengthening the network of clinical research professionals, enhancing the quality of the studies and empowering the community
 - Appropriate curriculum, professional development paths and also recognition of this career are essential

► [Trials](#). 2019 Oct 29;20(1):616. doi: 10.1186/s13063-019-3702-z.

European survey on national training activities in clinical research

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Survey conducted in 2019 in 11 ECRIN countries to describe the landscape of academic training opportunities.

- There was a substantial investment in training and education of clinical research in the individual ECRIN countries (national level)
- But a systematic approach for (top-down) strategic and overarching considerations was missing.



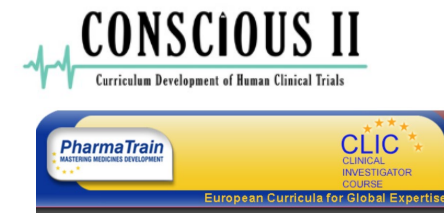
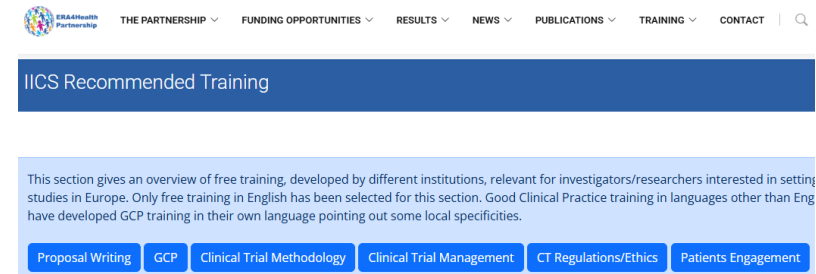
ACT-EU: CT training needs – survey to academia and SMEs

- Most important areas identified (CTR, GCP, safety & PV),
- Most frequent challenges (finding relevant training, lack of training for continuous education)

Already existing initiatives

- Overview of free trainings relevant for investigators & researchers interested in setting up IICS >> ERA4Health
- Trainings focused on generic curriculum development:
 - CONSCIOUS II: Curriculum Development of Clinical Trials for the Next Generation of PhD Students and Early Career Researchers in the Medical, Science, Pharmacy and Health Professions
 - CLIC program,
 - Joint Task Force for competency, ...
- Trainings focused in a specific area: most of the time embedded in EU funded projects (Vaccelerate, c4c, Permit, Sensitise, ERDERA...) contribute to increase scientific knowledge of the community >> issue of sustainability & upgrade

>> How do we ensure visibility/accessibility and maintain the existing opportunities to avoid duplication?



Next steps

Focus Group (FG) dedicated to the clinical trials training for academia and SMEs to contribute to shaping a sustainable training framework, ensuring that initiatives are tailored to the needs of academia and SMEs

Our suggestions:

- **Training framework should integrate:**
 - Priorities identified in the ACT-EU survey
 - Regulatory aspects for the **broad spectrum of clinical studies** (not only CTR/MDR/IVDR)
 - **Operational/technical aspects** (QMS, project management, risk-based approach, ...)
- **Training framework should be agile** i.e with modules adapted to different roles
- **Continuous improvement** in response to changing needs
- Training framework should include **training initiatives at EU and national level**

Supporting clinical trials across borders

