SCTO PLATFORMS

SPCRC
Swiss Professionals of Clinical Research Coordination

Competencies of clinical research study coordinator in Switzerland

	Competency domain	Junior study coordinator	Senior study coordinator	Lead study coordinator
1	**Study concepts and study design**	• Understand the difference between clinical trials, projects involving the collection of data/samples and projects with further use of data/samples. • Have basic knowledge in study designs. • Be able to differentiate between standard-of-care and research project/clinical trial activities.	• Understand the difference between clinical trials, projects involving the collection of data/samples and projects with further use of data/samples. • Have basic knowledge in study designs. • Be able to differentiate between standard-of-care and research project/clinical trial activities. • *Be able to categorise research studies according to Swiss law and interpret them accordingly.* • *Have good knowledge of study designs and their implementation.* • *Implement any study design in collaboration with Sponsor-Investigator.* • *Understand and analyse scientific concepts and research designs.*	• Understand the difference between clinical trials, projects involving the collection of data/samples and projects with further use of data/samples. • Have basic knowledge in study designs. • Be able to differentiate between standard-of-care and research project/clinical trial activities. • Be able to categorise research studies according to Swiss law and interpret them accordingly. • Have good knowledge of study designs and their implementation. • Implement any study design in collaboration with Sponsor-Investigator. • Understand and analyse scientific concepts and research designs. • *Provide input during design and protocol development at sponsor*

				site in investigator-initiated trials (IIT)
1.1	**Legislation**	• Have basic knowledge of national and international laws and guidelines that regulate human research.	• Have basic knowledge of national and international laws and guidelines that regulate human research. • *Understand and apply national and international laws and guidelines*.	• Have basic knowledge of national and international laws and guidelines that regulate human research. • Understand and apply national and international laws and guidelines. • *Assess and monitor regulatory compliance and intervene in cases of non-compliance.*

2	**Ethical guidelines and participant safety (ICH-GCP; Declaration of Helsinki, swissethics)**	• Have knowledge of the relevant national and international principles and regulations.	• Have knowledge of the relevant national and international principles and regulations. • *Apply and review relevant national and international principles and regulations in clinical trials and research projects.* • *Train new team members regarding ethical guidelines and participants' safety.*	• Have knowledge of the relevant national and international principles and regulations. • Apply and review relevant national and international principles and regulations in clinical trials and research projects. • Train new team members regarding ethical guidelines and participants' safety. • *Control and react in case of ethical non-compliance.* • *Implement ethical principles as well as participant protection and safety procedures during the conduct of clinical trials and research projects.* • *Plan regular updates of ethical principles in the research team.*

2.1	**Participant information and Informed Consent Form (ICF)**	• Know the study-specific participant information and the procedure around the ICF. • Be aware and understand the possible uses of the various ICF templates from swissethics.	• Know the study-specific participant information and the procedure around the ICF. • Be aware and understand the possible uses of the various ICF templates from swissethics. • *Ensure proper transmission of information to obtain proper informed consent from participants.* • *Train new team members regarding participant information process and ICF content.*	• Know the study-specific participant information and the procedure around the ICF. • Be aware and understand the possible uses of the various ICF templates from swissethics. • Ensure proper transmission of information to obtain proper informed consent from participants. • Train new team members regarding participant information process and ICF content. • *Ensure recurrent training and update of informed consent procedure for team members.* • *Formulate participant information and consent form in line with a research protocol at sponsor site in IIT.*

3	**Study Management**	• Know study procedures and the structure of a research protocol. • Understand and be aware of the possible uses of the various swissethics templates for research protocols. • Implement an existing research protocol with support where appropriate.	• Know study procedures and the structure of a research protocol. • Understand and be aware of the possible uses of the various swissethics templates for research protocols. • Implement an existing research protocol. • *Formulate amendments at sponsor site in IIT.* • *Submit research projects to EC via the BASEC portal at sponsor site in IIT.*	• Know study procedures and the structure of a research protocol. • Understand and be aware of the possible uses of the various swissethics templates for study protocols. • Implement an existing research protocol. • Formulate amendments at sponsor site in IIT. • Submit research projects to EC via the BASEC portal at sponsor site in IIT. • *Plan, implement and interpret scientific studies and research concepts.*
3.1	**Screening processes**	• Be aware of the importance and application of screening processes. • Perform the screening of research participants according to the protocol, the Standard Operating Procedures and good clinical practices.	• Be aware of the importance and application of screening processes. • Perform the screening of research participants according to the protocol, the Standard Operating Procedures and good clinical practices. • *Identify and address potential problems in the screening process.*	• Be aware of the importance and application of screening processes. • Perform the screening of research participants according to the protocol, the Standard Operating Procedures and good clinical practices. • Identify and address potential problems in the screening process. • *Define a screening process according to the research protocol and implement defined screening process into the routine processes.*

3.2	**Internal hospital processes**	• Know and apply the institution-specific **documentation** and patient related clinic systems.	• Know and apply the institution-specific documentation and patient related clinic systems. • *Train and educate new team members in internal hospital processes and study related processes.*	• Know and apply the institution-specific documentation and patient related clinic systems. • Train and educate new team members in internal hospital processes and study related processes. • *Develop and adapt clinic internal processes when implementing a research project and combining it with "routine" clinical work.*
3.3	**Stakeholder (Interest groups)**	• Identify study-specific processes, the various parties involved in the project and the associated contacts.	• Identify study-specific processes, the various parties involved in the project and the associated contacts. • *Communicate with all stakeholders.* • *Introduce stakeholders and their responsibilities to the study team.*	• Identify study-specific processes, the various parties involved in the project and the associated contacts. • Communicate with all stakeholders. • Introduce stakeholders and their responsibilities to the study team. • *Contact stakeholders for projects.*
3.4	**Resource management (staff, infrastructure, material)**	• Identify and be aware of study-specific resources.	• Identify and be aware of study-specific resources. • *Plan and manage resources*	• Identify and be aware of study-specific resources. • Plan and manage resources • *Assess resources, optimise efficient and economical use of resources*

3.5	**Documentation**	• Be aware of the importance of adequate documentation in studies	• Be aware of the importance of adequate documentation in studies. • *Ensure adequate documentation according to GCP.* • *Create study specific documents (Logs and forms).* • *Develop and manage Investigator Site File (ISF).* • *Manage Trial Master File (TMF) at the sponsor site in IIT.*	• Be aware of the importance of adequate documentation in studies. • Ensure adequate documentation according to GCP • Create study specific documents (Logs and forms) • Develop and manage ISF. • Manage TMF at sponsor site in IIT.
3.6	**Standard Operating Procedure (SOP)**	• Read, understand, and apply SOPs.	• Read, understand, and apply ƒSOPs. • *Develop and co-create standard operating procedures.*	• Read, understand, and apply SOPs. • Develop and co-create standard operating procedures.

4	**Data Management, Information Technology and Data Protection**	• Know guidelines on data management and data integrity. • Know and apply laws and guidelines on data protection.	• Know guidelines on data management and data integrity. • Know and apply laws and guidelines on data protection. • *Ensure contact with database operator/manager and ensure data integrity.*	• Know guidelines on data management and data integrity. • Know and apply laws and guidelines on data protection. • Ensure contact with database operator/manager and ensure data integrity. • *Communicate with database and IT management.* • *Have knowledge of information technologies and relevant softwares (including statistical programmes).* • *Monitor data protection and react in case of non-compliance*
4.1	**Source documents**	• Be aware of the significance and maintenance of study-specific source documents.	• Be aware of the significance and maintenance of study-specific source documents. • *Ensure adequate documentation based on research protocol*	• Be aware of the significance and maintenance of study-specific source documents. • Ensure adequate documentation based on research protocol. • *Check and ensure proper documentation in the existing source documents.*
4.2	**Case Report Form (CRF)**	• Know the difference between paper CRF (pCRF) and electronic CRF (eCRF).	• Know the difference between paper CRF (pCRF) and electronic CRF (eCRF).	• Know the difference between paper CRF (pCRF) and electronic CRF (eCRF).

		• Ensure accurate data entry and data correction according to GCP and/or study specific guidelines.	• Ensure accurate data entry and data correction according to GCP and/or study specific guidelines. • *Establish CRFs at sponsor site in IIT* • *Ensure adequate management of CRFs and compliance with requirements.*	• Ensure accurate data entry and data correction according to GCP and/or study specific guidelines. • Establish CRFs at sponsor site in IIT. • Ensure adequate management of CRFs and compliance with requirements. • *Ensure completeness of source documents according to protocol and their correct transfer into CRFs.* • *Ensure good communication with database management regarding data collection.*
4.3	**Safety (AE and SAE Forms)**	• Be able to define Adverse Events (AE), Serious Adverse Events (SAE) and other events according to protocol and applicable regulations.	• Be able to define Adverse Events (AE), Serious Adverse Events (SAE) and other events according to protocol and applicable regulations. • *Be able to recognise the various types of events.*	• Be able to define Adverse Events (AE), Serious Adverse Events (SAE) and other events according to protocol and applicable regulations. • Be able to recognise the various types of events. • *Support investigator in the documentation of events to appropriate authority (EC, Swissmedic).* • *Keep safety management updated in collaboration with investigator.* • *Train research team in safety issues.*

5	**Finances, Budget**	• Be aware of the existence of contracts, agreements, study compensation and material. • Control study invoices and forward them to the right partner.	• Be aware of the existence of contracts, agreements, study compensation and material. • Control study invoices and forward them to the right partner. • *Ensure compliance with contracts and agreements.* • *Provide support with the preparation of budgets and invoices.*	• Be aware of the existence of contracts, agreements, study compensation and material. • Control study invoices and forward them to the right partner. • Ensure compliance with contracts and agreements. • Provide support with the preparation of budgets and invoices. • *Support investigator in setting-up budgets, including negotiating with external companies/sponsors*
6	**Leadership, management, education and training**	• Follow GCP training and obtain GCP certificate (recommended). • Participate regularly in training opportunities. • Have knowledge of the research team and its responsibilities	• Follow GCP training and obtain GCP certificate (required). • Participate regularly in training opportunities. • Have knowledge of the research team and its responsibilities • *Train new research team members and function as internal contact point to maintain knowledge level of research team.*	• Follow GCP training and obtain GCP certificate (required). • Participate regularly in training opportunities. • Have knowledge of the research team and its responsibilities • Train new research team members and function as internal contact point to maintain knowledge level of research team. • *Share knowledge and master communication principles.* • *Ensure practical on-site tasks are delegated to appropriately trained research team members.*

7	**Quality assurance, quality control**	• Know the purpose for monitoring and quality control. • Provide support during the monitoring visits. • Process queries related to quality control.	• Know the purpose for monitoring and quality control. • Provide support during monitoring visits. • Process queries related to quality control. • *Be aware of existing monitoring plan processes.* • *Be a contact person for monitors*.	• Know the purpose for monitoring and quality control. • Provide support during monitoring visits. • Process queries related to quality control. • Be aware of existing monitoring plan processes. • Be a contact person for monitors. • *Ensure overview and actuality of the Quality Management System (QMS) including quality control and safety.* • *Ensure a monitoring plan is set up at sponsor site in IIT.* • *Supervise and manage inspections (audits).* • *Train research team for inspections (audits).*

8	**Networking and liaison function**	• Be a contact person for internal and external research related networks	• Be a contact person for internal and external research related networks • *Develop and maintain networks.* • *Make proactive use of networks.*	• Be a contact person for internal and external research related networks • Develop and maintain networks. • Make proactive use of networks. • *Ensure communication with all stakeholders for proper project and site management.* • *Set up and/or contribute to external networks.*
9	**Linguistic and social competencies**	• Understand research language / medical terminology. • Apply the basic rules of social interaction.	• Understand research language / medical terminology. • Apply the basic rules of social interaction. • *Be comfortable with spoken English*	• Understand research language / medical terminology. • Apply the basic rules of social interaction. • *Be fluent in English, both written and spoken*

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References:

- Clinical Research Professional Key Competencies. SOCRA: For Clinical Research Excellence. https://www.socra.org/resources-and-faq/core-competencies-2/ download 13.06.2021
- Competency Wheel in: Using the TDR Global Competency Framework for Clinical Research: A set of tools to help develop clinical researchers. WHO Document Production Services (DUP), Geneva, Switzerland. 2016
- Indices of Clinical Research Coordinators' Competence. Hornung CA, Ianni PA, Jones CT, Samuels EM, Ellingrod VL; DIAMOND Investigators.J Clin Transl Sci. 2019 Jun;3(2-3):75-81.
- 2016 Oncology Clinical Trials Nurse Competencies. ONS. Pittsburgh USA. www.ons.org
- Core Competencies of Clinical Research Coordinators. Kohara I et. Al..2017. Int. J of Bio-Science and Bio-Technology. 9/2. 1-10.
- Education and training of clinical and translational study investigators and research coordinators: A competency-based approach. Calvin-Naylor NA et.al. J Clin Transl Sci.2017 Feb;1(1):16-25.
- Gelling, L. (2008), Competency Framework for Clinical Research Nurses. A tool to promote patient safety and quality data. Pan Birmingham NHS Cancer Research Network: Birmingham.
- Juran`s Quality Handbook. The Complete Guide to Performance Excellence. Sixth Edition. Juran MJ, De Feo JA. The McGraw-Hill Companies. New York. 2010. ISBN: 978-0-07-162972-0
- SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Chan A et al. 2013. Ann Intern Med. 2013 February 05; 158(3): 200–207.
- ICH Quality Implementation Working Group Points to Consider (R2). ICH-Endorsed Guide for ICH Q8/Q9/Q10 Implementation. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. 2011. ICH Secretariat c/o IFPMA, Chemin Louis-Dunant 15, P.O. Box 195, 1211 Geneva 20, Switzerland. www.ich.org.
- Clinical Trials Transformation Initiative. (2017). CTTI QUALITY BY DESIGN PROJECT --- CRITICAL TO QUALITY (CTQ) FACTORS PRINCIPLES DOCUMENT. Version 19.05.2015