

## Clinical Trials Research Proficiency Skills

A site will be classified as 'Proficient' depending on its level of systems, management, and SOP development as either 'in development' or 'Proficient'. Proficiency status recognizes that a site is essentially self-sufficient and functions independently with systems in place that fully support protocol compliance, study implementation and has quality assurance checks in place that help it deliver high levels of compliance with both protocol and international standards. The site will be evaluated periodically on what systems and SOPs are in place and performance monitored as protocols are implemented.

This document outlines the skill sets required and performance indicators for achieving site proficiency in the conduct of Clinical Trials for the registration of new biological or pharmaceutical products for human use. Three additional complementary documents are:

- a) Site Management and Support Roles
- b) Site Capacity Development Road Map
- c) CTSS Support for Site Self Reliance.

These three documents were written with site self reliance as the ultimate goal.

- Through a participatory process, each site will be assessed at entry into the network or any other mutually agreed upon time and a baseline established for each skill
- To qualify as a proficient site not requiring routine CTSS assistance, a site should meet the standards outlined in this document
- As sites achieve the defined skill level in a task, they will no longer require routine assistance for that task from a CTSS
- Many of these systems are built on multiple subtasks that may require expansion as the study coordinator and CTSS create the Site Proficiency Plan as described in the Road Map.

Skill: The following systems are implemented at each study site	Key Systems Development Indicators KSDI	Site responsible team member	Performance Indicators For Site Independence (PISI) <i>(in development if less than proficient)</i>	Network Mentor/ Assessor <i>(indicate name or delegate)</i>
	1. Adequate staffing 2. Trained and understand rules 3. SOPs in place 4. QA/QC checks	<i>*PI is ultimately responsible for all aspects of performance related to clinical trial</i>		
<b>Regulatory Compliance</b>				
1. Understand rules and regulations for international and national clinical research requirements	1. Site has adequate staff. PI or SC or knowledgeable site staff is/are responsible for the regulatory compliance 2. Site staff have been trained for local and international laws and/or regulations related to clinical research. 3. Pertinent local and international regulatory guidelines available 4. Site develops QA/QC plan including timeline projection and troubleshooting for any findings; site has internal QA system to ensure documents are properly filed.	PI or Study coordinator	<ul style="list-style-type: none"> <li>Designated staff have attended GCP training, received passing scores.</li> <li>Designated staff have received training in Research Ethics</li> <li>Guidelines and reference materials for local FDA available</li> </ul>	NCC training coordinator or local country designee and CTSS
2. Submissions <ul style="list-style-type: none"> <li>Protocols</li> <li>Safety/ AE/ SAE reports</li> <li>Protocol violations</li> </ul>		Study coordinator	100 % complete all submissions within timeline	NCC Clinical Research Manager or local country designee and CTSS
3. Regulatory document: compiling and maintaining essential documents		Study coordinator and Research Assistant	Self function for filing and maintaining essential documents	NCC Clinical Research Manager or local country designee and CTSS
4. Understands in-country/local IRB requirements and IRB requirement for submissions		PI and Study coordinator	Compliance with in-country/local IRB requirements. Local IRB reference documents available on-site. Exhibits an understanding of local IRB guidelines.	CTSS and NCC designee

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<b>Financial Management</b>				
5. Financial System Management	<ol style="list-style-type: none"> <li>1. Site has adequate staff for financial duties.</li> <li>2. Designated staff have been trained in basic financial management and allowable costs by NCC Financial officer</li> <li>3. Pertinent local and international accounting guidelines available</li> <li>4. Site develops tracking system for budgeted costs and spent costs AND has a payment tracker in place; QA/QC system in place for ensuring financial data are accurate and complete</li> </ol>	Study accounting manager/lead accountant and/or study coordinator	Creating budget per protocol AND provide Network participation costs	NCC Financial officer or local country designee

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Protocol Implementation				
6. Informed Consent process	<ol style="list-style-type: none"> <li>1. PI, Co-I, SC or RN</li> <li>2. Staff have been trained to obtain the consent from subjects particularly the vulnerable subjects and participated in study specific training.</li> <li>3. SOP or Guideline on obtaining informed consent is on file and implemented and appropriately updated.</li> <li>4. Internal QC and External QC plan is on file. Site has monitoring system to ensure the procedures are conducted in compliance with the SOP</li> </ol>	Medical staff and research team	<ul style="list-style-type: none"> <li>• Obtain IC and document properly, no significant critical findings per individual subject consent process</li> <li>• Staff have demonstrated proficiency in the SOP.</li> <li>• Appropriate training has taken place and there is evidence/documentation that appropriate people have participated</li> </ul>	NCC Clinical Research Manager or local country designee and CTSS
7. Conducting protocol and other relevant research activities in compliance with study procedures	<ol style="list-style-type: none"> <li>1. PI, Co-I, SC or RN</li> <li>2. Staff obtain the study specific training and understand relevant process</li> <li>3. Site SOP or MOP is on file and implemented</li> <li>4. Internal and External QA/QC is established and monitored</li> </ol>	PI and research team	Have been monitored by independent monitor with no critical finding	NCC Clinical Research Manager or local country designee and CTSS

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	<ol style="list-style-type: none"> <li>1. Adequate staffing</li> <li>2. Trained and understand rules</li> <li>3. SOPs in place</li> <li>4. QA/QC checks</li> </ol>			
<p>8. Laboratory system (Routine clinical laboratory)</p> <ul style="list-style-type: none"> <li>▪ Specimens handling and collection</li> <li>▪ Lab result and reporting system</li> <li>▪ Tracking and Filing</li> </ul>	<ol style="list-style-type: none"> <li>1. Site has adequate number of trained Lab staff</li> <li>2. Training               <ol style="list-style-type: none"> <li>a. Study staff received training on specimen collection, transport and delivery to the laboratory.</li> <li>b. Laboratory staff received training on both (i) routine and (ii) study specific specimen storage and laboratory tests.</li> <li>c. Laboratory staff records and fills all lab form as per protocol.</li> </ol> </li> <li>3.               <ol style="list-style-type: none"> <li>a. Study specific SOPs, chain of custody and other standard SOPs such as GCLP, equipment maintenance, safety etc are followed and a copy is available to staff who does the work.</li> <li>b. SOP in place to protect participant confidentiality</li> </ol> </li> <li>4. EQA, PT or CAP panels are available, data analyzed and corrective measure taken. Site develops a QA program to assure staff are following SOPs.</li> </ol>	Study coordinator, Lab Director and/or designated laboratory staff	<ol style="list-style-type: none"> <li>1. No of staff available for project specific laboratory work.</li> <li>2.               <ol style="list-style-type: none"> <li>a. Training certificate or documents of proof of training.</li> <li>b. Training certificate or proof of training as well as adherence to MOP.</li> </ol> </li> <li>3. SOPs present in file and practice of adherence to SOPs are observed during visits.</li> <li>4. EQA, PT panels are received and tested in time, results are being analyzed and kept in file. Corrective measures are in place and documented.</li> <li>5. Aim towards ISO certification as a goal</li> </ol>	NCC local country lab representative
<p>9. Pharmacy system</p> <ul style="list-style-type: none"> <li>▪ Pharmacy Plan</li> <li>▪ Pharmacy facility</li> <li>▪ Study drug handling and dispensing</li> <li>▪ Tracking and filing</li> <li>▪ Inventory control</li> </ul>	<ol style="list-style-type: none"> <li>1. Pharmacist and back up pharmacist</li> <li>2. Staff obtain training and understand protocol specific procedures</li> <li>3. Pharmacy plan including study drug handling and other SOPs are on file and implemented</li> <li>4. Internal and External QA check is implemented</li> </ol>	Principal Pharmacist, Dispenser of Record, Back-up Pharmacist (see Pharmacy PI), Study coordinator	Pharmacy Plan and SOPs implemented for three months after the first participant enrolled for at least one network study at the site.	Pharmacist Committee local country representative

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10. Data Management <ul style="list-style-type: none"> <li>▪ Source documentation completion</li> <li>▪ CRF completion and Data Transfer</li> </ul>	<ol style="list-style-type: none"> <li>1. SC, DM, data entry staff or admin staff</li> <li>2. Staff understand the data flow, data completion and obtain protocol specific data handling</li> <li>3.               <ol style="list-style-type: none"> <li>a. SOP for site specific data management plan is on file and implemented</li> <li>b. SOP for source documentation is on file and implemented</li> <li>c. Protection of participant confidentiality is part of the relevant SOPs</li> </ol> </li> <li>4. Internal and External QA/QC system (transcription error, data transfer timeline) to monitor the data quality is on file and implemented</li> </ol>	Study coordinator	<b>Source Document Completion:</b> <ul style="list-style-type: none"> <li>• Staff have demonstrated proficiency in the SOP</li> </ul> <b>Data Transfer:</b> <ul style="list-style-type: none"> <li>• CRF and query transferred to DMU within timeline</li> </ul>	NCC Clinical Research Manager or local country designee and CTSS

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<b>Site Management</b>				
11. Patient management <ul style="list-style-type: none"> <li>▪ Patient identification (depend on study/protocol)</li> <li>▪ Patient referral plan</li> <li>▪ Patient Flow</li> <li>▪ Patient retention</li> <li>▪ Patient tracking</li> </ul>	1. PI, CO-I, SC, RN or designated hospital staff 2. Staff obtains protocol specific training or documentation on the emergency medical care training. Understand study process, visit schedule and research procedures 3. Study SOPs or site management plan for participant recruitment and retention is on file and implemented 4. Internal and External monitoring system are followed.	PI and study coordinator	<b>Patient Recruitment</b> Subject identification strategies have been in place; be able to adjust strategies according to current situation. Site implements the QA/QC activity <b>Patient Flow:</b> Patient flow has been in place for a minimum of 3 months, be able to adjust flow according to current situation <b>Patient Retention:</b> Strategies have been in place for a minimum of 3 months, be able to adjust strategies according to current situation <b>Patient Tracking:</b> Tracking forms have been utilized for a minimum of 3 months	NCC Clinical Research Manager or local country designee and CTSS

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12. Team management	<ol style="list-style-type: none"> <li>1. Applies to all team members</li> <li>2. <ol style="list-style-type: none"> <li>a. All staff understand their roles and responsibilities and each persons unique contribution to the team's success, success of the trials and safety and best interests of the patient participants.</li> <li>b. All staff have job descriptions that are regularly reviewed and updated;</li> <li>c. all personnel have job performance indicators and performance is regularly reviewed.</li> </ol> </li> <li>3. Communication plan within the site (each department, IRB) and with the network (sponsor, protocol team, pharmacovigilance) is in place</li> <li>4. Administrative QA plan to ensure regular meetings , information dissemination and performance review (can be informal plan).</li> </ol>	PI and SC	<ul style="list-style-type: none"> <li>• All staff understand their roles and responsibilities</li> <li>• Teams meet regularly and discussions of issues and problems are encouraged; team works together to solve problems</li> <li>• Regular performance review and feedback.</li> </ul>	NCC CO team leader or designee and CTSS
13. Network Participation	<ol style="list-style-type: none"> <li>1. PI and/or lead staff</li> <li>2. Staff participates in the meeting, calls and all correspondences. Meeting minutes are kept in the site administrative file</li> <li>3. Network manual is on file and implemented</li> <li>4. Site staff confirm participation in Network meetings through discussion at their site team meetings.</li> </ol>	PI	<ul style="list-style-type: none"> <li>• Network level: PI/Site staff or representative participate in relevant committee calls more than 50% of the time; key staff serve on committees, or have expressed willingness to serve on a committee.</li> <li>• Country-level: Site PI/staff participate in country level team meetings with other sites</li> </ul>	NCC CO team leader or designee

**References:**

- Site Management and Support Roles
- Site Capacity Development Road Map
- Site Preparation Plan
- Site Opening Checklist
- SEA ICRN Network Manual
- ICH-GCP Guidelines
- US Code of Federal Regulations Title 21 Parts 11, 50, 54, 56, 312, 314