

1. The following is from “A Manual: CTSS Support for Site Self Reliance” (26 May 2008)

Roles Specific to the Site Qualification Plan [this activity is in development and is not yet in operation]

Each site will develop a Site Qualification Plan (described in the Site Capacity Development Road Map); the PI, Study Coordinator and CTSS will work closely to create and implement the Plan. The steps are:

- The CTSS evaluates, or assesses, the site’s knowledge and experience performing specified tasks necessary to the conduct of clinical research according to NCC requirements, using a standard checklist and system created by the NCC
- Based on the results of this assessment, the current experience level of the site will be determined, and a qualitative experience ranking will be assigned (to identify a baseline level of experience of low, moderate or high)
- The site will determine its own goals for capacity development (depending on its own needs and situation)
- The PI, Study Coordinator, and CTSS will then develop a Site Qualification Plan that ensures the site meets the minimum performance standards of the Network, and sets training and infrastructure improvement targets, with timelines, to reach the site goals
- The CTSS and Study Coordinator will work together to conduct appropriate training and create needed systems to work towards full site competence
- The CTSS will periodically evaluate the site on the tasks and the Plan, on a schedule specified in the Plan, to determine improvements; the Plan will be updated according to progress
- When a site can fully accomplish a specified task on its own, the CTSS will update the Plan to certify the site has completed the training on that task

2. The following is from: “Site Development Road Map” (26 August 2008)

Expectations for Site Performance: The Road Map

Successful management of a clinical research site is challenging especially when the regulations and procedures are not familiar. Each research site in the Network has agreed to conduct research according to ICH GCP guidelines and the policies and procedures of the Network, as well as specified rules and regulations of the US government and their local government agencies.

The Network is dedicated to assisting its research sites achieve successful study implementation according to all these standards. The goal of the Network is to help the sites build their own research skills to the point of becoming independent from external

assistance from the NCC. This skill building is a process that involves engaged participation from the site PI, his/her site research staff, and the NCC.

- Sites will be evaluated according to a set of accepted international standards outlined by the NCC, and its level of readiness and competency in the various standards rated
- The site PI will work closely with his/her study coordinator, the NCC Country Office and the Clinical Trials Support Specialist (CTSS) to develop a Site Qualification Plan to achieve higher levels of competency in each of the site responsibilities
- The study coordinator and CTSS will work together to provide any necessary training and develop appropriate systems to achieve higher competencies
- When a site can fully accomplish a designated responsibility on its own, the CTSS will update the Plan to certify the site has completed the training on that task
- As the site gains experience it will advance through the Plan and achieve greater independence

Sites will be recognized at the Network level for completing the Site Qualification Plan.

Site Responsibilities and Competencies

Sites will be evaluated for the following competencies against development standard and performance indicators noted in Table 1.

Assessing Baseline Site Capacity Levels and Creating the Site Self-reliance Plan

Sites will be evaluated according to established development and performance criteria at the initial site assessment or at a later date if site is already a Network member.

Assessment dates will be mutually agreed upon between PI, NCC and responsible CTSS. The evaluation team will be composed of a member of the NCC, the responsible CTSS and the SC. The team will out-brief with the PI and study team at the completion of the review and together wherever possible immediately develop plan for establishing necessary skills and competencies. There will be a periodic re-assessment every six (6) months to follow-up on areas requiring attention as well as a general review to ensure maintenance of key skills and systems that already meet site self-reliance standards.

At the time of the initial evaluation, the evaluating team will meet with the PI and selected members of the study team, forming a working group. Site status in the various competencies will be reviewed with the team in detail and consensus reached regarding the missing elements. Missing elements might include staff additions, specific training or certification, equipment or facilities improvements. An action plan will be developed with the PI, appropriate team members, NCC staff and CTSS. The plan will include a timeline, milestones and indicators for success. If there are unanticipated expenditures associated with plan, a budget will be submitted to the NCC for funding approval. The PI, SC, CTSS and NCC will work together toward meeting the milestones outlined in the qualification plan. There will be semi-annual evaluations but the working group will monitor developments at the site more regularly and seek to solve problems, remove obstacles to the achievement of the desired objective on schedule.