Guidance for MTAA Abbreviated Curriculum Vitae (CV) Template

Background

This CV Template was created to capture research staff qualifications. To help streamline efficiencies for Investigative Sites the MTAA and member companies have agreed to accept this version of an Abbreviated CV for use in Clinical Trial documentation.

Use

Use is not mandatory, but rather is being provided as a convenience for Investigators and Site staff to use if creating an abbreviated CV.

Contents

- The abbreviated CV template is not intended to be a comprehensive CV.
- The CV template is an abbreviated CV; it collects the necessary information regarding an individual's qualifications for conducting clinical studies with respect to education, training and most relevant clinical study experience in the space provided.
- Additional description of key fields is detailed below:

Job/Professional Title: Represents the current role of the individual with respect to the clinical study. There are only two options – either Clinical Investigator or Clinical Research User

Address: Needs to reflect the primary business address.

Facilities Affiliations: This is any institution where the individual performs paid or unpaid professional services. The clinical research facility where the clinical trial is being performed should be included. Enter a facility and add any departments.

Education: Enter any degrees or certificates. For medical education, add specialty if applicable.

Professional Experience: This should include current and previous relevant positions, including academic positions

Job Title: This is the formal designation of the role held by the individual at their institution/place of employment

License Details: This should include details on any medical license or national code of identification that are held

Good Clinical Practice Training Details: Enter completed GCP Training. Maintaining a current GCP certificate (dated within three years) is recommended.

Research Experience:	Enter details on your Clinical Study research experience
Study Type:	Select all types of studies which you have experience conducting
Clinical Study Phases:	Select all phases for which you have experience
Therapeutic Areas of Expertise:	Should include all therapeutic areas in which the individual has expertise
Total Clinical Research Experience:	Should include a list of completed and ongoing clinical studies by therapy area
Signature:	Signatures can be electronic or wet ink and should be contemporaneous (within previous 12 months) with the start of the sponsors clinical trial.

General Considerations

- A Sponsor should inquire if the site has previously completed a TransCelerate CV Template or if it is a user of SIP. If it is a user of SIP, the site can export abbreviated CVs directly from the system and utilize that for use in a Medical Device trial, rather than develop a new version from scratch.
- Once completed, the CV should be issued by the site to the requesting Sponsor.
- The site should be instructed to keep a copy of each CV and upon repeat request, review and update the content, sign, date, and send to the new requestor.