

## Frequently Asked Questions – last updated 11<sup>th</sup> December 2009

- **Why become certified?**

- 1) Being able to demonstrate you have the relevant background and underpinning knowledge (for example to a prospective employer or an external auditor).
- 2) To demonstrate to potential customers that you have the required underpinning knowledge, education, and experience to undertake the work (for example when a CRO is bidding for work).
- 3) To reinforce “credibility” with investigational sites and increase your confidence that the information and practices you are implementing aligned with industry best practices and aligned with ICH-GCP and Australian requirements.
- 4) Taking a leadership position with regards to a better trained and capable workforce (particularly if you are in charge of a team of more junior employees)

- **The resource pack limits clinical resource certification to those employed by sponsor companies. What about research site staff?**

Research site staff will be eligible to apply for clinical research certification as soon as the relevant competencies are finalised. This is anticipated for mid-2010.

- **I have completed equivalent clinical research training programs in my company. Can I become an ARCS Certified Member?**

Yes. You will be required to pass the ARCS knowledge assessments and provide supporting documentation detailing the courses completed. A fee will apply.

- **What is a certificate of completion?**

A certificate of completion is issued to an attendee who has passed an assessment associated with an ARCS educational events (which may include a conference, computer based training program, workshop etc)

- **I hear that there is only a certification process available for those in clinical research? What about non-clinical staff?**

Regulatory Certification pathway has been developed, and like clinical we hope to be able to endorse an international accreditation as well. Plan to roll this out in early 2010.

- **What about other disciplines?**

ARCS' Certification is recognition of training and experience. For those disciplines where we don't have a complete training program we will work with ESCs to develop this. Pharmacovigilance is likely to be the next group to have Certification and we are considering this in conjunction with a Medical Affairs certification pathway. Health Economics is also being scoped.

- **What is the transition situation?**

People who have completed the introductory ARCS courses (Overview of Drug Development and CRA 1 - Essential GCP Training for New CRAs) since 1 July 2008 will be eligible for Certification on completion of the remainder of courses.