DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE

Powered by MTPConnect

Researcher Exchange & Development within Industry (REDI)

Request for Proposals to Meet Priority Skills Gaps in the Medical Technology, Biotechnology & Pharmaceutical Sector

REDI CONTESTABLE PROGRAM- ROUND 1 | GUIDELINES | NOVEMBER 2020

MTPConnect
MedTech and Pharma Growth Centre

Australian Government
Department of Health
Medical Research Future Fund

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1. OPPORTUNITY, OVERVIEW AND OBJECTIVES

Australia's Medical Technology, Biotechnology and Pharmaceutical (MTP) sector supports around 70,000 Australian jobs and contributed more than $5 billion in Gross Value Added (GVA) to the Australian economy in 2019. Its future is dependent on the skills of its workforce.

This opportunity is made possible under the Researcher Exchange and Development within Industry (REDI) program which is an initiative of the Australian Government's Medical Research Future Fund (MRFF). REDI has undertaken a comprehensive analysis of skills gaps in the Medical Technology, Biotechnology and Pharmaceutical (MTP) sector and identified several critical skills gaps that inhibit the industry maximising the impact on healthcare in Australia. This Request for Proposal (RfP) calls for suitably qualified organisations to submit programs to address the skills gaps identified and detailed in this RfP.

1.1 About the Medical Research Future Fund

As part of the 2014-15 Budget, the Australian Government announced the establishment of the MRFF, a $20 billion fund to support medical research and medical innovation to improve the health and wellbeing of Australians. The MRFF was established through the *Medical Research Future Fund Act 2015*.

MRFF funding targets identified national priorities (the Australian Medical Research and Innovation Priorities) determined by the independent Australian Medical Research Advisory Board consistent with the *Medical Research Future Fund Act 2015*. Investments made from the MRFF cover the entire research pipeline from basic to applied research with a focus on the translation and commercialisation of discoveries. The Medical Research Future Fund Funding Principles underpin the MRFF and ensure it continues to support investments that are priority driven, strategic, collaborative and contestable with a focus on maintaining research integrity.

The intended outcomes of the MRFF are:

- Life changing discoveries such as new treatments, drugs and devices;
- Continuous improvement and innovation in the health system that benefits all Australians;
- Strengthening domestic research capacity through support, collaboration and the development of expert talent;
- Positioning Australia's health and medical research sector at the forefront of the innovation economy; and
- Improving Australia's reputation as a global leader in health and medical research.

1.2 About the Researcher Exchange and Development within Industry (REDI) Program

MTPConnect operates the REDI program for the MRFF, leveraging the expertise of our research, training and industry partners to drive skills development and workforce training, through deployment of an integrated, three-pillar plan. The four-year REDI program, initiated in June 2020, will:

- Deliver systemic improvement to Australia's MTP workforce by providing industry experiences and skills development for researchers, clinicians and innovators;
- Develop an industry-ready workforce with the skills necessary to keep pace with a rapidly changing sector;
- Provide a skills development blueprint across the MTP value chain through a 'root and branch' skills gap analysis; and
- Create new training, mentoring and industry placements over the life of the program.

Pillar One: Expansion of Proven Programs
MTPConnect is partnering with training, mentoring, internship, entrepreneurship and incubator organisations to support expansion of their proven training programs to deliver deeper impact by addressing known skills gaps. Expansion of the training programs will create more industry placements, mentoring and researcher exchange programs and will reach greater numbers of early and mid-career researcher and clinical researchers. Partner organisations include:

- MedTech Actuator;
- The Industry Mentoring Network in STEM (IMNIS) program;
- The Medical Device Partnering Program (MDPP); and
- ANDHealth.

Pillar Two: Identifying unknown skills gaps and implementing new programs
REDI is delivering a forward-looking 'root and branch' analysis of the MTP workforce to provide a deep understanding of current and future skills gaps. The analysis is an essential step in preparing Australia's MTP workforce to meet future demands. Informed by MTPConnect's 2020 Sector Competitiveness Plan and linking with national MTP industry and research bodies, the analysis forms the foundation for a contestable program of new initiatives to fill skills gaps not currently addressed. Partner organisations include:

- The George Institute for Global Health; and
- Victorian Comprehensive Cancer Centre (VCCC).

Pillar Three: Industry placements, internships and fellowships
To ensure workforce skills align with industry needs and drive industry-research-clinical-entrepreneurship connections, the REDI program is providing targeted short, medium and long-term industry placements, internships and fellowships for clinicians, early stage, mid-career and distinguished researchers and MTP professionals, enabling high-performing individuals from these cohorts to gain industry experience. Industry placements will focus on discovery, translation and commercialisation of relevant research. Partner organisations include:

- APRIntern; and
- The Bridge and BridgeTech programs.

2. KEY FOCUS

This RfP is aligned with REDI Pillar 2: Identifying unknown skills gaps and implementing new programs, which is designed to support programs that close skills gaps identified in sector-wide workforce analysis.

On **13 November 2020**, MTPConnect opened a call for Proposals for training and/or education courses to meet urgent needs across specified skills gaps identified in the Interim Report of the REDI program Skills Gap Analysis. This RfP calls for programs capable of closing the identified gaps as well as the national implementation/ delivery of these programs.

Proposals are sought from:

- Companies with capability in these areas;
- Industry Associations;
- Registered Training Organisations; and
- Universities.

It is incumbent on the successful Bidder to ensure delivery targets are met.
Proposals are sought for courses addressing skills in the following areas:

- **Understanding of quality management systems and protocols**; and
- **Strategic design of clinical trials to meet regulatory and payer needs**.

The full details of the courses required are outlined in *Appendix 1: Course Overviews*. Please note that some Proposals may cover single and/ or multiple courses.

The outcomes of these programs are to:

- strengthen Australia's success in terms of translation and commercialisation of health and medical research; and
- expand the capacity and capability of the research community to undertake translational health and medical research.

The focus is to ensure the maximum impact of investment into the sector. As such, the successful Bidder will need to report on participant feedback about the quality of the course and application of new skills and knowledge within the workplace. There is an emphasis on the right participants undertaking the course.

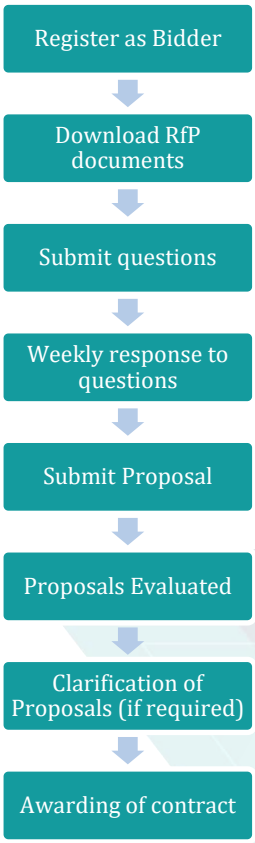
For all face to face courses and programs, it is expected that the participant will make a co-contribution towards their tuition fees.

3. PROCESS

Applications to Round One of the REDI Contestable program (REDIC1.0) will be conducted through a one-step Request for Proposal process, as follows:

- Potential Bidders will download the Request for Proposal and Bidding Documents through the REDI section of the MTPConnect website;
- MTPConnect will host an information webinar shortly after the Opening of the RfP;
- Questions and clarifications can be submitted by email to redic.proposal@mtpconnect.org.au;
- All Bidders questions and responses will be uploaded weekly to the Bidding Documents on the REDI section of the MTPConnect website; and
- Bidders will submit a binding proposal through the online application portal prior to the proposal closing date. Bidders can access Proposal 1 and/or Proposal 2 directly. Proposals are valid for 90 days from the closing date. Eligible Proposals will be

reviewed by an independent selection panel of research and industry experts. The selection panel will evaluate the proposals based on the defined scoring criteria and generate a rank ordered list of applications. The panel reserves the right to clarify points in submissions and negotiate on the deliverables and price before final awarding of the contract.



At any time, MTPConnect reserves the right to withdraw the RfP or not to award, or to delay awarding the programs listed in *Appendix 1*.

4. ELIGIBILITY CRITERIA

To be eligible for consideration, applications must satisfy all the requirements set out in this Guidelines document.

For a Proposal to be deemed eligible for REDIC1.0 funding, it must:

1. Come from an Australia based organisation – has an Australian Business Number (ABN);
2. Have a track record in delivering impactful training and education programs;
3. Come from an Australia based organisation that is financially sound;
4. Meet any applicable timing, formatting, system or other similar administrative requirements imposed by MTPConnect;
5. Advise that the proposed funding recipient will adhere to the terms and conditions of funding set out in a partnership agreement as determined by MTPConnect; and

6. Be received in full on or before the closing date. Late or incomplete applications will not be accepted.

A Proposal may be considered ineligible and excluded from further consideration if it:

a. Does not meet the objectives of the program;
b. Fails to address one of the identified focus; and/or
c. Contravenes an eligibility rule or other requirement as set out in this Guidelines document.

5. REQUIRED DOCUMENTS

Proposals should be submitted as two documents (Technical Proposal and Financial Proposal) and address all the selection criteria outlined in Item 6. The Selection Criteria.

The **Technical Proposal** covers Sections 1, 2 and 3 of the Selection Criteria. There is no template provided for this response. However, it is required to include a Provider Fact Sheet (see *Appendix 2*) and it must be in the body of the Technical Proposal. CV's, testimonials and supporting documentation should be included as appendices. Bidders are urged to carefully consider their response so all criteria are adequately addressed. The Proposal has a page limit of 20 A4 pages **plus** appendices. CV's are limited to 3 A4 pages each.

The **Financial Proposal** needs to be completed using the attached template. If costs such as venue, catering, training materials, etc. is required, it must be included in the price. Bidders are encouraged to submit different prices for the home state/s delivery and interstate delivery of programs – where appropriate reflect savings of delivery in home states. For non-wholly online courses, participants are expected to pay a nominal fee which needs to be included in your Financial Proposal. If domestic travel restrictions impact interstate delivery of courses, and these courses are delivered completely virtually, the home state pricing will be paid. We strongly recommend that Bidders carefully consider their risk and/or pricing strategy when completing the Financial Proposal.

6. THE SELECTION CRITERIA

The following selection criteria will be used to assess Proposals.

Proposal Selection Criteria		Weighting
Section 1:	***Understanding and experience*** The proposal will be evaluated based on: a. Understanding of the topic; b. Experience delivering training programs; c. Feedback from participants in similar training programs; d. Quality systems, processes and continuous improvement; and e. Testimonials.	**10%**
Section 2:	***Approach to solve issue*** The proposal will be evaluated based on: a. Approach to the training program; b. Key challenges and/or obstacles and mitigation strategies; c. Details of the training program; d. Incorporation of andragogic principles; e. Ability to penetrate target market; and f. Course details if COVID-19 impacts on domestic travel or face to face delivery.	**40%**
Section 3:	***Team*** The proposal will be evaluated based on: a. Bio's/ input of facilitators/ trainers/ lecturers; a. Clear definition of roles and responsibilities of project team; and b. Bio's/ input of project staff. Please note: the bulk of this score is assessed on the facilitator/ trainer/ lecturer.	**30%**
Section 4:	***Value for money*** The proposal will be evaluated based on: a. Value for money.	**20%**

7. USE OF FUNDING

Project funding is paid on contract signing and then in-line with milestones/ submitted reports which will be finalised in the contracting phase.

Commonwealth Funding provided through the REDI program can only be spent on eligible expenditures incurred on eligible activities during the term of the partnership agreement and in accordance with the Commonwealth Terms & Conditions for Standard Funding Agreement (March 2015).

You can only spend grant funds on eligible expenditure you have incurred on an agreed project as defined in your grant agreement.

Not all expenditure on your project may be eligible for grant funding. The program delegate makes the final decision on what is eligible expenditure and may give additional guidance on eligible expenditure if required.

To be eligible, expenditure must be:

- incurred by you within the project period;
- a direct cost of the project; and
- incurred by you to undertake required project audit activities.

Eligible expenditure items can include:

- direct labour costs of employees you directly employ on the core elements of the project. We consider a person an employee when you pay them a regular salary or wage, out of which you make regular tax instalment deductions;
- contract expenditure is the cost of any agreed project activities that you contract to others;
- domestic travel limited to the reasonable cost of accommodation and transportation required to conduct agreed project activities in Australia;
- staff training that directly supports the achievement of project outcomes; and
- other eligible expenditure as approved by the program delegate.

Examples of ineligible expenditure include:

- expenses associated with business as usual activities not related to the delivery of the project;
- financing costs, including debt financing and interest;
- costs involved in the purchase or upgrade/hire of software (including user licenses) and ICT hardware (unless it directly relates to the project);
- non-project-related staff training and development costs;
- costs related to obtaining resources used on the project, including interest on loans, job advertising and recruiting, and contract negotiations;
- costs related to preparing the grant proposal, preparing any project reports and preparing any project variation requests; and
- this list is not exhaustive and applies only to the expenditure of the grant funds.

8. HOW TO APPLY

Proposals must be submitted online through the MTPConnect online application portal.

Bidders can access Proposal 1 and/or Proposal 2 directly.

Proposals will open at **09.00hrs (AEDT) on Friday, 13 November 2020**.

Proposals received after **17.00hrs (AEDT) on Tuesday, 15 December 2020** will not be considered. Any additional attachments or repeated submissions for the same project will not be accepted.

All Proposal applications received will be acknowledged automatically upon submission and Bidders will be provided with an Identification Number to be referenced in all future communications in relation to the application.

Bidders requiring further assistance should contact **Jarrod Belcher, Director REDI Program** on +61 402 456 301 or at REDIC.proposal@mtpconnect.org.au.

9. NOTIFICATION OF APPLICATION OUTCOMES

Bidders will be notified of the outcomes of their Proposal by **Friday**, **26 February 2021** and those successful will enter into negotiations with MTPConnect.

Successful Bidders will receive a written offer which will include specific conditions attached to the grant.

The Federal Minister for Health may publicly announce successful Bidders and may include name of the business, project title and description, amount of funding awarded. Details of successful Bidders may also be published on the MTPConnect and Department of Health's websites.

10. THE PARTNERSHIP AGREEMENT & IP

The successful Bidder must enter into a legally binding partnership agreement with MTPConnect in the form of the MTPConnect Partnership Agreement.

Any reports and materials delivered to MTPConnect will be subject to a non-exclusive use licence to MTPConnect and the Commonwealth for their purposes.

MTPConnect must execute a partnership agreement with the Bidder before any payments can be made. Bidders must not start any project activities until a partnership agreement is executed.

The partnership agreement may be extended. This will be based on participant numbers and outcomes of the programs reported against the objectives and outcomes of the REDI program.

11. PROJECT SPECIFIC LEGISLATION, POLICIES & INDUSTRY STANDARDS

Bidders are required to be compliant with all relevant laws and regulations, including those specified in the Commonwealth Grant Agreement between the Commonwealth and MTPConnect.

The Bidder will be required to complete a risk assessment and undertake clearance checks to demonstrate and ensure that its personnel are in compliance with legislative requirements for working with children and vulnerable persons.

To the extent that the project involves collecting and using personal information, the Bidder will be required to comply with privacy requirements; including obtaining appropriate consents for the collection, storage and use of personal information.

It is a condition of the funding that all Bidders meet these requirements and these requirements will be set out in Bidders' partnership agreement with MTPConnect.

MTPConnect may be subject to Freedom of Information (FOI) requests and, if such a request is made, MTPConnect will consult with the Bidder before any decision is made to release the application or supporting documentation.

12. FUNDING ACQUITTAL & REPORTING

The Bidder will be required to provide regular project and financial reports and audits to MTPConnect to demonstrate its delivery of the project, financial acquittal and compliance with the partnership agreement.

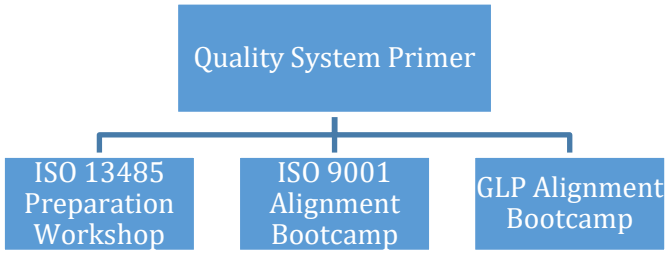
MTPConnect will monitor and report progress of successful Bidders to the Commonwealth. Funding will be tied to reporting obligations. MTPConnect will make payments according to an agreed schedule set out in the partnership agreement. Payments are subject to satisfactory milestone-progress on the project.

Bidders will be required to submit reports in line with the partnership agreement. The reports must include data/ feedback based on the Impact Assessment Framework (IAF). MTPConnect will monitor the progress of a Bidders' project. MTPConnect may conduct site visits or request information or records to confirm details of Bidders' reports as necessary.

APPENDIX 1 REDI PILLAR 2 COURSE OVERVIEWS

Proposal 1: Understanding of quality management systems and protocols

This Request for Proposal is a **single proposal** covering the **four (4) courses** detailed below.



It is expected that the participants will attend the **Quality System Primer** Course and following this they can attend either one of the Workshop/ Bootcamps aligning to their needs or if the participant is sufficiently aware of their needs and commits their time to attend the correct Workshop/ Bootcamp directly.

Quality System Primer

Course Overview:

This course explains the benefits of having a quality system for researchers, SME's and clinicians considering translating research to a product. It highlights examples of where research without a quality system has negatively impacted commercialisation. It outlines the four most relevant accredited quality systems for MTP commercialisation and where each of these are relevant.

Delivery Method	Course Duration	Who should attend
Online	2 – 3 hours	Researchers, SME's, Start-ups Suppliers and Clinicians

Course Content:

- Overview of Quality Management systems relevant to the MTP sector
- Reasons for quality systems
- Benefits of quality system certification and of alignment with a quality system
- What ISO 13485 covers and who it is for
- What ISO 9001 covers and who it is for
- What ISO 17025 covers and who it is for
- What Good Laboratory Practice (GLP) covers and who it is for

Course Objectives:

After completion of this course, participants will be able to:

- Describe if a quality system benefits their work
- Choose what quality system alignment best suits their needs
- Commence the process to implement an accredited or non-accredited (but aligned) quality system

Delivery:

Must deliver a 1-year license for an unlimited number of participants across Australia.

400 participants must undertake the online training.

ISO13485:2016 Preparation Workshop

Course overview:

This course is for manufacturers and companies intending to manufacture medical devices and is their first step on the path to ISO 13485:2016 accreditation. It is suitable for manufacturers and companies with existing quality system accreditations (such as ISO 9001:2015) as well as those with no existing accreditations. It is also applicable to staff in companies with existing ISO 13485:2016 accreditations who have a role in implementing the system.

This course will provide participants with the knowledge and process steps to enable them to effectively implement a quality management system and to meet the requirements for ISO 13485:2016 certification.

Delivery Method	Course Duration	Who should attend
Face to Face or Blended	Minimum of 4 days	Leaders and staff from companies interested in manufacturing medical devices

Course Content:

- Overview of Quality Management systems, particularly ISO 13485:2016
- Benefits of quality system certification and of alignment
- Purpose, structure and requirements of ISO 13485:2016
- Overview of application process for ISO 13485:2016
- Development of some documentation required for ISO 13485:2016
- Preparation for applying for ISO 13485:2016
- Archiving

Course Objectives:

After completion of this course, participants will be able to:

- Describe the fundamentals of ISO 13485:2016
- Explain the purpose, structure and requirements of ISO 13485:2016
- Apply a process of implementing a quality management system that meets the requirements of ISO 13485:2016
- Complete several documents needed for ISO 13485:2016 accreditation
- Prepare for ISO 13485:2016 certification

Delivery:

Must deliver one course in each state to a minimum of 10 pax per course.

REDI will provide funding up to 25 pax per course (maximum class size).

ISO9001:2015 Alignment Bootcamp

Course overview:

This course is for organisations, companies and institutes in the MedTech Pharma sector that want to increase / document the quality and reproducibility of their systems and work. This course is not just for workplaces who are planning to obtain ISO 9001:2015 accreditation, but are wanting to implement a quality system fit for their own needs and purposes. Graduates will be well placed to commence the accreditation journey should they choose.

It provides an overview of ISO 9001:2015 Quality Management Standard (QMS) and how these can be applied in the MedTech Pharma environment. It will provide insights into key clauses and concepts that underpin an effective QMS. The course will enable participants to commence their journey to implementing an effective QMS aligned with ISO 9001:2015.

Delivery Method	Course Duration	Who should attend
Face to Face or Blended	Minimum of 3 days	Leaders, staff, researchers, clinicians from research institutes, universities, laboratories and companies with an interest in translating research

Course Content:

- Overview of Quality Management systems, particularly ISO 9001:2015
- Benefits of quality system certification and of alignment to ISO 9001:2015
- Purpose, structure and requirements of ISO 9001:2015
- Development of QMS system scaffold
- Development of QMS documentation
- Following QMS system
- Archiving

Course Objectives:

After completion of this course, participants will be able to:

- Describe the fundamentals of an ISO 9001:2015 aligned quality management system
- Document operations and activities
- Apply a process of implementing a quality management system that aligns with ISO 9001:2015
- Implement a QMS
- Plan and conduct audits

Delivery:

Must deliver one course in each state to a minimum of 10 pax per course.

REDI will provide funding up to 25 pax per course (maximum class size).

Good Laboratory Practice (GLP) Alignment Bootcamp

Course overview:

This course is for organisations, companies, institutes and laboratories in the MedTech Pharma sector that want to increase /document the quality and reproducibility of their systems and work. This course is not just for workplaces who are planning to obtain GLP accreditation but are wanting to implement a laboratory quality system fit for their own needs and purposes. Graduates will be well placed to commence the accreditation journey should they choose.

This course will provide an overview of GLP standard and how these can be applied in the MedTech Pharma environment. It will provide insights into key clauses and concepts that underpin an effective QMS. The course will enable participants to commence their journey to implementing an effective QMS aligned with GLP.

Delivery Method	Course Duration	Who should attend
Face to Face or Blended	Minimum of 3 days	Leaders, staff, researchers, clinicians from research institutes, universities, laboratories and companies with an interest in translating research

Course Content:

- Overview of Quality Management systems, particularly GLP
- Benefits of quality system certification and of alignment
- Purpose, structure and requirements of GLP
- Development of QMS system scaffold
- Development of QMS documentation
- Following QMS system
- Archiving

Course Objectives:

After completion of this course, participants will be able to:

- Describe the fundamentals of an GLP aligned quality management system
- Document operations and activities
- Apply a process of implementing a quality management system that aligns with GLP
- Implement a QMS
- Plan and conduct audits

Delivery:

Must deliver one course in each state to a minimum of 10 pax per course.

REDI will provide funding up to 25 pax per course (maximum class size).

Proposal 2: Strategic design of clinical trials to meet regulatory and payer needs

This Request for Proposal is a **single proposal** covering **two (2) courses**. The first course is focused on medical devices with the second course focused on pharmaceuticals. The course content and objectives are similar for both courses with the difference being that one course is specific to medical devices and the second to pharmaceuticals.

Clinical trial design to meet regulatory and payer needs

Course overview:

This course prepares participants to understand the factors that impact design of clinical trials and evidence generation plans to meet the requirements of regulators and consider the payors requirements. At the completion of the course, participants will be able to assess evidence-generation process to ensure that necessary information is at hand to make pricing, reimbursement and product-positioning decisions. The program will be interactive involving workshops, case studies and a simulation giving participants experiential learning that they will be able to quickly translate into their work environments.

Delivery Method	Course Duration	Who should attend
Face to Face or Blended	Minimum of 5 days	Start-Ups (founders), SME's (leaders with responsibilities for appointing Clinical Trial partners and/or strategy development), commercialisation executives, clinicians and researchers. This course is not primarily for Clinical Trials Specialists.

Course Content:

- Inputs required to design trial program (such as regulatory, health economics, statistics, pre-clinical data)
- Clinical trials as part of evidence generation plan
- Components of a clinical trial
- Good Clinical Practice
- Clinical trial design strategies
- Examples of clinical trials for different outcomes
- Novel designs including adaptive trial design
- Stakeholder analysis
- Environmental scan, competitor landscape and how this impacts design
- Comparators
- Case Studies
- Simulation
- Regulator requirements around the globe

Course Objectives:

After completion of this course, participants will be able to:

- Explain the phases of clinical trials
- Detail different trial design strategies including novel designs such as adaptive trial design
- Compare and contrast clinical trial designs for different outcomes
- Demonstrate an in-depth understanding of the different regulators and payers around the globe and data required
- Describe different clinical trial strategies and their purposes
- Demonstrate an in-depth understanding of the proper management of a clinical trial and the steps needed to ensure maintenance of the highest levels of good clinical research practice
- Understand the inputs required/ stakeholder involvement in clinical trial design/conduct including benefits of cross functional team input
- Describe the ethical and regulatory process required for the conduct of a clinical trial by analysing appropriate and inappropriate research conduct
- Comprehend complex scientific information and communicate advanced concepts in written and oral form

Delivery:

Must deliver each course nationally for up to 30 pax per course (maximum class size).

APPENDIX 2 PROVIDER FACT SHEET

Provider Fact Sheet			
Company Name			
Partner/s (if applicable)			
Lead Entity ABN			
Address			
Website			
Main Contact & Position			
Phone Number			
Email			
Alternative Contact & Position			
Phone Number			
Email			
Number of Years Operating			
Financials	Item/ Year	FY20	FY19
	Revenue		
	Overall Debt		
	Debt to Equity Ratio		