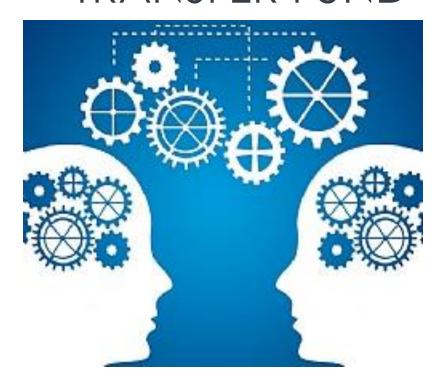
# UWISTA INNOVATION AND TECHNOLOGY TRANSFER FUND



3/19/2020

# **OPERATIONAL GUIDELINES**

ST AUGUSTINE CENTRE FOR INNOVATION AND ENTREPRENEURSHIP (STACIE)
THE UNIVERSITY OF THE WEST INDIES, ST. AUGUSTINE

# 1 OVERVIEW AND SCOPE

- 1.1 In 2017, The University of the West Indies (The UWI) adopted a new 'Triple A' Strategic Plan 2017-2022. Focusing on the three pillars of Access, Alignment and Agility, the plan identified several key strategic goals related to accelerating research commercialization at the UWI campuses. In particular, the plan identifies increasing the number of patents and spinoffs as key metrics of success in the implementation of the strategic plan.
- 1.2 To this end, The UWI St Augustine Campus (UWISTA) conceptualized the formalization of an Innovation and Technology Transfer (ITT) Fund, to be managed by the St Augustine Centre for Innovation and Entrepreneurship (STACIE).
  - (a) At a meeting of the UWI St. Augustine Campus Finance and General Purposes Committee held on July 26<sup>th</sup>, 2017, the Committee approved in principle the establishment of an Innovation and Technology Transfer (ITT) Fund *subject to* identification of source of funds and the implementation of a governance structure.
  - (b) At the subsequent meeting of the UWI St. Augustine Campus Finance and General Purposes Committee held on 22<sup>nd</sup> September 2017, the Committee authorized that funds previously set aside for research projects that have remained unutilized, for at least three (3) years, and during that time were not subject to relevant requests for project extensions from the project investigators, be redirected to capitalize the Innovation and Technology Transfer (ITT) Fund. The Committee further directed that communication be made with recipients of grants who had not utilized funds within the stipulated period, and for the succeeding three (3) years, that the funds would be re-allocated and that if there were projects that were on-going, the Campus should be notified of those cases, with well-supported documentation outlining the extenuating circumstances for consideration.
- 1.3 The Fund was capitalized and is sustained by UWISTA itself through the redirection of unencumbered residual funds from closed special projects as outlined above, in the first instance.
  - (a) At the meeting of the UWI St. Augustine Campus Finance and General Purposes Committee held on July 26<sup>th</sup>, 2017, the Committee agreed that in order for the Bursar or assignee to initiate the Residual Balance Transfer process, the Faculty or relevant Department, Unit, Centre or Institute office needs to provide and/or confirm the following:
    - i. All work was completed.

- ii. No outstanding work activities or deliverables remain open or in question by the sponsor (and expenses are in accordance with the terms and conditions of the agreement and the negotiated budget).
- iii. All required technical reports were received and/or accepted by the sponsor.
- iv. All invoices/ financial reports for the project were submitted and all payments have been received by The UWI.
- v. All budgeted expenditures and payments to external contractors, staff, departments and institutes have been charged to the award.
- vi. Signature of the Dean, Director or Designate approving the residual balance transfer.
- 1.4 The ITT Fund is intended to provide more deliberate and strategic support for technology transfer and research commercialization activities, given the lack of attention these types of activities have previously been afforded at UWISTA. This Fund would allow the STACIE to be more agile and responsive to research commercialization opportunities that arise at UWISTA as well as allow for exploiting synergies and economies of scale in addressing costs associated with research commercialization.
- 1.5 ITT Fund awards are intended to support the development of intellectual property (IP), inclusive of ideas, technologies, know-how and inventions, with a view to commercializing and/or licensing the resultant innovations if deemed viable upon project completion. The IP which forms the basis of the funding request must be owned or co-owned by The University of the West Indies and subject to relevant IP disclosure processes and requirements and/or an executed legal agreement.
- 1.6 The ITT Fund is designed to accelerate the transformation of proven innovations and technologies into commercial products, processes and services. The Fund will support activities which enable progression from proof of concept to investment ready innovations which have been adequately developed, validated, scaled and de-risked, ready to be transitioned to commercial development.

# 2 GOVERNING FRAMEWORK

- 2.1 The ITT Fund is set up with a dual governance structure:
  - i. The Secretariat, to be appointed from within the STACIE, will be responsible for the day-to-day management of the ITT Fund. The Secretariat will also be responsible for the administration of the ITT Fund, inclusive of disseminating general information on the Fund, compiling requests for funding, preparing evaluation packages for the Fund Evaluation Committee, and periodic reporting on the performance of the Fund. A small percentage (5%) of the annual fund allocation will be used to support the ITT Fund's administration by the ITT Fund Secretariat. Additionally, periodic financial audits,

- evaluations and performance assessments by independent experts shall be commissioned by the Secretariat to ensure monitoring and evaluation of approved projects and financial transparency and accountability.
- ii. The Fund Evaluation Committee will serve as the Board of the ITT Fund and provides oversight of all Fund activities. It will set policy direction for the Fund and conduct the technical assessment of eligible funding requests. The Fund Evaluation Committee will be the main decision-making body regarding the management of the ITT Fund and its administration by the Secretariat. The Evaluation Committee will be chaired by the Director, STACIE and shall comprise the Campus Bursar (or nominee), the Campus Principal's Nominee (to be selected from UWISTA Staff), and at least two representatives from the public and/or private sector (business/industry/ investment). The Fund Evaluation Committee may co-opt specially invited business experts and/or members of the investment community to assist in the review and evaluation of requests for funding. Technical and/or industry experts may also be invited to assist in the review and evaluation process where appropriate.
- 2.2 To prevent potential conflicts of interest, members of the Fund Evaluation Committee shall not serve as members of teams submitting requests for funding from the ITT Fund.
- 2.3 Members of the Secretariat shall attend meetings of the Evaluation Committee as observers to support the administration of the review and evaluation process and to document decisions taken. The Secretariat may also be asked to provide guidance on approved funding/approval/disbursement criteria and procedures, and other matters related to the management of the ITT Fund and its reporting.
- 2.4 Meetings of the Fund Evaluation Committee
  - i. **Evaluation Meetings** These are convened within 2-4 weeks following the close of a Call for Applications (subject to the availability of the members of the Fund Evaluation Committee) to select and shortlist successful Applications for Funding Consideration. The approval of full Funding Request Proposals will be done on a rolling basis (as the completed applications are submitted) with the technical review and final approval being conducted electronically via 'round robin'.
  - ii. **Progress Review Meetings** These may be convened periodically for the Evaluation Committee to be updated on progress made with the execution of activities within each approved project against approved project timelines and milestones. Team Leaders may be invited to deliver presentations to members of the Fund Evaluation Committee.
  - iii. **Special Meetings** These may be called to review existing policies or guidelines that govern the activities of the ITT Fund and/or approve new policies, guidelines or activities. Since funding requests will be accepted on a rolling basis as well as during active calls for applications, special meetings may also be called to evaluate requests that come in outside of an active call. Special meetings may also be convened to facilitate discussions with representatives of potential donor agencies who wish to support the ITT Fund.

- 2.5 The management of the ITT Fund shall be guided by governance mechanisms approved by the Fund Evaluation Committee to preserve the integrity of the ITT Fund's application, evaluation and approval processes and to ensure transparency and accountability to all stakeholders.
- 2.6 The Fund Evaluation Committee reserves the right to review and amend the Operational Guidelines of the ITT Fund as needed to provide an effective framework for the management of the ITT Fund's activities.

# 3 FINANCING

- 3.1 The maximum amount that can be requested in a single funding request under the ITT Fund is **TT\$1M**. Competitive proposals for funding consideration will include matching non-UWI funds.
- 3.2 The maximum duration of a project is **18 consecutive months** from the date stated on the letter of approval from the ITT Fund. The maximum execution time would only be granted for projects that present a compelling case for such an execution timeline.
- 3.3 Disbursements shall be linked to achievement of project milestones and these shall be outlined in the approved terms of the award as part of the approved implementation schedule.
- 3.4 The financial award under the ITT Fund shall be considered a grant. However, should the IP which forms the basis of the funded request be successfully commercialized, a first charge on income generated from the commercialization of said IP, claimed as recovery costs by The UWI by virtue of its ownership or co-ownership of the intellectual property (IP) in question, will be a full reimbursement in the total amount of the grant awarded for the project to the ITT Fund to replenish funding and ensure the sustainability of support for research commercialization and technology transfer at UWISTA.

# 4. ELIGIBILITY

- 4.1 Any staff or student member at UWISTA may serve as Team Leader and submit a funding request to the ITT Fund.
- 4.2 Funding requests will be accepted from all fields of research. Activities which address the priority research areas of UWISTA, the national development goals of Trinidad and Tobago, and/or the Sustainable Development Goals are particularly encouraged.
- 4.3 The Team Leader must ensure that an invention disclosure form and/or a legal agreement has been submitted to the STACIE disclosing the IP upon which the funding request is based,

either prior to or concurrent with the application to the ITT Fund for funding consideration. Competitive requests will already have IP protection (e.g. copyright, provisional patent, patent) for the IP which forms the basis of the funding request.

- 4.4 The IP which forms the basis of the funding request must be owned or co-owned by The UWI.
- 4.5 In the case of collaborative proposals, ownership of IP must be settled prior to commencement of funded activities. A signed legal agreement outlining the nature of the collaboration and the potential sharing of royalties must be submitted to the Fund's Secretariat before the initial disbursement of the financial award. Award letters in this case will be considered conditional upon the receipt by the Secretariat of a signed collaboration agreement within **three** (3) **months** of the date on the award letter.
- 4.6 The innovation or technology which forms the basis of the funding request should be in the technology readiness level range 5-9<sup>1</sup> with an already identified commercial application and should preferably have proven economic feasibility and a completed technology assessment.
- 4.7 Competitive funding requests must identify distinct, perceptible barriers to commercialization and propose discrete and defined activities, with accompanying tangible milestones, which seek to eliminate the hurdles identified.
- 4.8 The Team Leader shall have responsibility for ensuring technical quality, and shall be accountable to The UWI St. Augustine Campus on all matters pertaining to effective and timely execution and reporting as well as financial management.
- 4.9 UWI research Institutes, Centres and Units are eligible to submit proposals once the Team Leader is based at The UWI, St. Augustine Campus.
- 4.10 Components of the project executed by team members of other UWI Campuses and/or other institutions shall be channeled through the Team Leader for reporting purposes or the processing of disbursements related to the specific component.
- 4.11 Given that the focus of this ITT Fund is supporting research commercialization, protected or proprietary research results should not be publicised until a determination is made on the exploitation of the IP which forms the basis of the proposal as well as any IP generated during

<sup>&</sup>lt;sup>1</sup> For the purposes of the ITT Fund, Technology Readiness Levels (TRLs) will be defined as follows (based on definitions developed by the National Aeronautics and Space Administration (NASA) available here <a href="https://www.nasa.gov/sites/default/files/trl.png">https://www.nasa.gov/sites/default/files/trl.png</a>

TRL 1 Basic principles observed and reported

TRL 2 Technology concept and/or application formulated

TRL 3 Analytical and experimental critical function and/or characteristic proof of concept

TRL 4 Technology validation in laboratory environment

TRL 5 Technology validation in relevant environment

TRL 6 Technology model or prototype demonstration in a relevant environment

TRL 7 Prototype demonstration in an operating environment

TRL 8 Actual technology completed and qualified through test and demonstration

TRL 9 Actual technology proven through successful operational deployment

the funded activities, and on the commercial viability of the innovation or technology which formed the basis of the funding request. Publication and dissemination strategies should be developed with the STACIE so as not to compromise the commercial viability and competitiveness of the technology or invention.

4.12 Resulting publications from activities supported by the ITT Fund must include a funding acknowledgement. While the exact wording will depend on the format stipulated by the publisher, the following text is recommended:

"This work was supported by The University of the West Indies, St Augustine Campus' Innovation and Technology Transfer Fund."

### 4.13 Intellectual Property and Commercialization

The UWI Policy on Intellectual Property Management and Commercialization and the University Financial Code shall be applicable to approved activities funded by the ITT Fund. The policy documents are available online at:

https://sta.uwi.edu/ordkt/documents/UWIIPPOLICYREVISIONFINALVERSIONAPPROV EDBYUNIVERSITYFGPCMAY2015VERS2.pdf and http://uwi.edu/sf-docs/default-source/finance-docs/Revised Financial Code Aug 13 2008.pdf?sfvrsn=0

### 4.14 Research Ethics

The UWI Policy on Research Ethics shall be applicable to activities supported by the ITT Fund. This policy document is available online at:

https://sta.uwi.edu/ordkt/documents/UWIPolicyonResearchEthics.pdf

### 4.15 Code of Ethics and Conflicts of Interest

The UWI Statement of Principles/ Code of Ethics for Academic and Senior Administrative Staff and the University Bluebook shall be applicable to team leaders and team members involved with activities supported by the ITT Fund. The policy documents are available online at:

https://sta.uwi.edu/hr/documents/Statement of Principles Code Of Ethics for Academic and Senior Administrative Staff.pdf and https://sta.uwi.edu/hr/documents/bluebook-may2015.pdf

# 5 USE OF FUNDS

- 5.1 Team leaders will be responsible for ensuring that they adhere to the approved Use of Funds proposal and the associated approved budget. Failure to do so may result in the termination of the award.
- 5.2 Amendments to the Use of Funds proposal and/or changes to the approved budget may be considered by the Evaluation Committee following the submission of a written request with justification.
- 5.3 Changes to the approved scope, activities and implementation schedule may not be undertaken without the prior approval of the Evaluation Committee following the submission of a written request with justification.
- 5.4 Budget expenses incurred before the award date will **not** be reimbursed.
- 5.5 Unexpended funds shall return to the ITT Fund.
- No-cost extensions shall only be granted for extenuating circumstances and requests for such an extension should be made in writing six (6) months prior to the expiration of an award for consideration by the Evaluation Committee. Extensions will not be granted for more than 6 months.

### 5.7 Eligible Expenditure Items Include:

i. Consultancies/short-term contracts for services that are essential to achieving the outcomes earmarked in the various components of the project. This may include support for post-doctoral scholars and current PhD students performing the duties of Research Assistants. Research assistantships, consultancies and other types of service contracts (whether for an individual or a firm) shall be guided by the UWI Financial Code. Procurement of eligible and/or approved goods (materials, equipment etc.) shall also be guided by the UWI Financial Code as well as the UWISTA Procurement Policies and Procedures Guide. These policy documents are available at:

https://sta.uwi.edu/cpo/guidelines.asp and http://uwi.edu/sf-docs/default-source/finance-docs/Revised Financial Code Aug 13 2008.pdf?sfvrsn=0

- ii. Inputs/ingredients, chemicals and other materials related to the conducting of experiments and/or sample testing;
- iii. Project-related equipment (shall become the property of the UWI St. Augustine Campus and shall comply with the UWI Asset Management policy guidelines);
- iv. Expenses related to travel and/or the organization of meetings during project execution are only eligible if they are **required** to conduct project activities (shall be in keeping with existing UWI travel policies/guidelines);

- v. Expenses related to print, electronic or radio advertisement and/or other media marketing and PR related activities;
- vi. Legal costs and negotiation costs;
- vii. Expenses related to obtaining IP protection;
- viii. Business formation expenses;
- ix. Sales and general business operating expenses, manufacturing and distribution;
- x. Independent evaluations of commercialization potential;
- xi. Independent valuations of start-ups and licensable technologies;
- xii. Professional services (legal, accounting, insurance, etc.);
- xiii. Business plans, market research and development;
- xiv. Product and service design/ development/ differentiation;
- xv. Sourcing and development of a management team/ board of directors/ mentors;
- xvi. Salaries;
- xvii. Prototype development/optimization;
- xviii. Iterations, Pivots, Ensuring product market fit;
  - xix. Rent.

### 5.8 **Ineligible Expenditure Items Include**:

- i. Acquisition or upgrade of any land, property or vehicle;
- ii. Consultancies or short-term contracts for persons who are already full-time employees of the UWI;
- iii. Consultancies or short-term contracts for persons who are full-time employees of other institutions shall be consistent with the policies in force at those institutions or shall otherwise be deemed ineligible. In such cases, the written consent of the partner institution shall be submitted to the ITT Fund Secretariat for the preparation of the relevant contracts;
- iv. Honoraria and/or appearance fees for guest speakers at meetings, conferences or other project-related events;
- v. Travel to attend academic conferences or present research findings;
- vi. Publication costs;

- vii. Reimbursements for personal funds spent on project-related items or activities. [However, Faculty or Departmental advances, not exceeding TT\$10,000, which are related to approved project activities, shall be eligible for reimbursement];
- viii. Personal telephone bills, ICT tools and/or products such as cell phones, laptop computers, etc.;
- ix. Contingencies shall not be recognized as an expenditure line item in approved budgets;
- x. Departmental or Faculty charges not related to the execution of activities as stated in the approved funding request and itemised in the approved budget shall not be eligible for payment from approved project funds.

# 6 APPLICATION AND EVALUATION PROCESS

- 6.1 Applications for funding consideration will be accepted on a rolling basis as well as in response to calls for funding applications. Applications submitted in response to an active call will not be accepted by the ITT Fund Secretariat for consideration in that call if submitted beyond the stipulated deadline.
- 6.2 Reviewers will be asked to sign non-disclosure and non-compete agreements. However, protected or proprietary information **should not** be included in applications and proposals submitted for funding consideration but should provide sufficient information for reviewers to make a determination regarding commercialization potential.
- 6.3 The Team Leader shall firstly submit an Application for Funding Consideration outlining the basis of the funding request for evaluation by the ITT Fund Evaluation Committee. The template for the Application for Funding Consideration is available from the ITT Fund Secretariat.
- 6.4 The assessment of the Application for Funding Consideration shall be based on the following criteria:
  - Technical quality
    - Strength of the IP that currently exists and/or will be generated
    - Clearly defined hurdle to commercialization
    - Appropriate technology readiness level
    - Can the proposed project deliverables reduce investor risk
    - Will requested funding enable commercialization

- Discrete programme of work identified
- Appropriateness of funding amount and implementation timeline
- Appropriateness of the proposed strategy and the associated activities

### Team characteristics

- Technical and entrepreneurial expertise of the team
- The commercialization interest of the project leader and team members
- Demonstrated familiarity with current competing or emerging innovations/ technologies
- Interest from industry partners
- Multi-disciplinary/cross-Faculty/cross-Campus/ industry collaboration and/or other strategic partnerships
- Participation of students engaged in research
- Commercialization potential of the project
  - Project's proximity to commercialization
  - Demonstrated effort spent on customer discovery
  - Demonstrated industry need
  - Market attractiveness, particularly to global markets
- 6.5 Each Application for Funding Consideration will be scored and ranked individually by members of the Evaluation Committee, reviewed and considered during the deliberations of the Evaluation Committee before arriving at a consensus on the Applications to be shortlisted.
- 6.6 Team Leaders whose Applications are shortlisted may be invited to do a pitch presentation to the Evaluation Committee if deemed necessary to aid the deliberation process.
- 6.7 Teams whose Applications are successful shall be invited to submit a detailed Funding Request Proposal for review and consideration for funding by the Evaluation Committee. The template for the Funding Request Proposal is available from the ITT Fund Secretariat. Funding Request Proposals submitted without an invitation will not be reviewed.
- 6.8 Teams whose Applications were unsuccessful but whose projects were considered to have high potential and merit may be asked by the Fund Evaluation Committee to re-submit a revised and/or updated Application to a subsequent Call for Proposals or redirected to a more appropriate source of funding. Critiques of unsuccessful Applications will not be provided.
- Once submitted before the stipulated deadline, the Fund Evaluation Committee shall review the Funding Request Proposals and consider the extent to which each project proposal has

- adequately met the criteria outlined in section 6.4 and satisfactorily provided the additional details required in the full Proposal.
- 6.10 **Proof of Market (PoM) Grants**, up to a maximum of TT\$200,000, may be awarded at the discretion of the Evaluation Committee via a simplified application process to pursue market validation, regulatory, and/or other activities necessary to advance the commercialization readiness level (CRL)<sup>i</sup> of the IP which forms the basis of an Application for Funding Consideration, as deemed appropriate by the committee after evaluation of the application.
- 6.11 Teams under consideration to receive Proof of Market Grants will not have to submit a Funding Request Proposal. Evaluation of the request and the subsequent funding decision will be made based on the Application for Funding Consideration and the invited pitch. The project idea which forms the basis of the request should be at the CRL 1-5<sup>i</sup>.
- 6.12 Teams awarded Proof of Market Grants will be expected to advance their project IP's CRL in some specific manner<sup>i</sup>, as indicated by the committee when communicating their funding decision, before a detailed Funding Request Proposal can be entertained.
- 6.13 Letters of approval shall be forwarded to the Team Leader within 1 week of the final decision of the Evaluation Committee.
- 6.14 Approved Proposals which require the facilitation and cooperation of UWI Faculties, Departments, Units, Centres or Institutes (UCI) must be submitted to the Head/Director of relevant Department/s and/or UCIs and the Dean of the corresponding Faculty for noting and non-objection.
- 6.15 The approved Proposal must then be forwarded to the Bursary for registration and the assignment of a Project Code in preparation for the commencement of approved activities.

### 7 GRANTEE RESPONSIBILITIES

- 7.1 Successful Team Leaders will be required to sign and return a copy of their award letter to the ITT Fund Secretariat, signifying their agreement and ability to comply with the terms and conditions of the award.
- 7.2 Teams shall submit quarterly progress reports to the ITT Fund Secretariat every three (3) months and attend progress monitoring meetings with the Secretariat when requested. The template for the Progress Report is available from the ITT Fund Secretariat. The Secretariat shall issue notices to alert team members of the due date for the next Progress Report. Subsequent funding tranches shall only be disbursed following the receipt and acceptance of the respective Progress Reports and the achievement of pre-approved milestones. Failure to complete the stipulated milestones and approved project deliverables may result in delays in payment and additional disbursement as well as the potential termination of the award.

- 7.3 Completion Reports shall also be submitted to the ITT Fund Secretariat within 2 months of the approved completion date of the award. This report will provide a complete update on the achievement of the approved milestones and deliverables. It will also present evidence to support a conclusive decision on the commercial viability of the project (inclusive of actionable market application, market validation and viable business model) and propose next steps. Invention disclosures for any new inventions or other IP generated during the course of the project should be submitted concurrent with the completion report, if it had not been done previously. The template for the Completion Report is available from the ITT Fund Secretariat. The Team Leader and team members shall be at the disposal of the ITT Fund to participate in close-out meetings, press conferences, fundraising events, stakeholder forums, pitches, special distinguished lectures, etc. to report on and promote their commercialization work and the outcomes of the funded activities.
- 7.4 Successful Team Leaders must demonstrate significant investment in learning about strategies for commercializing their intellectual property and increasing their business management skills. This should be done through independently sought out learning opportunities and/or through organized capacity building activities organized or identified by the STACIE.
- 7.5 Successful teams are expected to make use of the commercialization support provided by the STACIE throughout the duration of the grant.

<sup>i</sup> Defined by the United States Department of Energy Advanced Research Projects Agency-Energy (ARPA-E) Knowledge of applications, use-cases, and market constraints is limited and incidental, or has yet to be obtained at all. CRL 2 A cursory familiarity with potential applications, markets, and existing competitive technologies/products exists. Market research is derived primarily from secondary sources. Product ideas based on the new technology may exist, but are speculative and unvalidated. CRL 3 developed understanding of potential applications, technology use-cases, requirements/constraints, and a familiarity with competitive technologies and products allows for initial consideration of the technology as product. One or more "strawman" product hypotheses are created, and may be iteratively refined based on data from further technology and market analysis. Commercialization analysis incorporates a stronger dependence on primary research and considers not only current market realities but also expected future requirements. CRL 4 A primary product hypothesis is identified and refined through additional technology-product-market analysis and discussions with potential customers and/or users. Mapping technology/product attributes against market needs highlights a clear value proposition. A basic cost-performance model is created to support the value proposition and provide initial insight into design trade-offs. Basic competitive analysis is carried out to illustrate unique features and advantages of technology. Potential suppliers, partners, and customers are identified and mapped in an initial value-chain analysis. Any certification or regulatory requirements for product or process are identified. CRL 5 A deep understanding of the target application and market is achieved, and the product is defined. A comprehensive cost-performance model is created to further validate the value proposition and provide a detailed understanding of product design trade-offs. Relationships are established with potential suppliers, partners, and customers, all of whom are now engaged in providing input on market requirements and product definition. A comprehensive competitive analysis is carried out. A basic financial model is built with initial projections for near- and long-term sales, costs, revenue, margins, etc. CRL 6 Market/customer needs and how those translate to product needs are defined and documented (e.g. in market and product requirements documents). Product design optimization is carried out considering detailed market and product requirements, cost/performance trade-offs, manufacturing trade-offs, etc. Partnerships are formed with key stakeholders across the value chain (e.g. suppliers, partners, customers).

	All certification and regulatory requirements for the product are well understood and appropriate steps for compliance are underway. Financial models continue to be refined.	
CRL 7	Product design is complete. Supply and customer agreements are in place, and all stakeholders are engaged in product/process qualifications. All necessary certifications and/or regulatory compliance for product and production operations are accommodated. Comprehensive financial models and projections have been built and validated for early stage and late stage production.	
CRL 8	Customer qualifications are complete, and initial products are manufactured and sold. Commercialization readiness continues to mature to support larger scale production and sales. Assumptions are continually and iteratively validated to accommodate market dynamics.	
CRL 9	Widespread deployment is achieved.	

# DOCUMENT CONTROL

Current Version (V2)	Approved 3/19/2020
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