

Activities	Commercialization Activities Content	TREAT Academy Expanded Learning Objectives
Business Development		
Need and Opportunity Analysis	Identification of potential risks, documentation of market size and growth trends, identification of external stakeholders	<ul style="list-style-type: none"> • Understanding regulatory and reimbursement schemas as related to neural medical devices
Customer Discovery	Definition and validation of core business assumptions based on stakeholder needs, conducting and summarizing interviews	<ul style="list-style-type: none"> • Patient-centered device development • Fighting cognitive bias, objective evaluation of the innovation
Market Requirements	Translate customer interview data into a market requirements document	<ul style="list-style-type: none"> • Validating and confirming market requirement assumptions
Business Model Development	Design for the successful operation of a business including revenue, customers, costs, and financing, pro forma financials	<ul style="list-style-type: none"> • Assess and secure intellectual property • Team gap analysis
Business Model Validation	Verifying business model assumptions via insight from product development	<ul style="list-style-type: none"> • Confirming that prototypes meet market requirements
Marketing, Sales & Distribution	Execution of business activities focused on revenue generation, inventory management, and product sales and marketing	<ul style="list-style-type: none"> • Customer relationship management, including offering provider/patient education and support

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Clinical Evaluation		
Clinical Rationale	Justification of clinical need, impact from opinion leaders, policies, and published evidence. Understanding clinical pathways	<ul style="list-style-type: none"> • Evidence synthesis to prove the needs and impact, clinical proof of concept • Bioethical considerations
Quality Management	Framework to document and manage development decisions	<ul style="list-style-type: none"> • Application of good manufacturing practices and quality management
Concept Evaluation	Confirmation that the technology concept meets market requirements	<ul style="list-style-type: none"> • Identification of key features that meet stakeholder requirements
Regulatory and Reimbursement Strategy	Understanding the requirements of regulatory bodies and planning to meet the evidence standards or technical specifications to obtain third-party payment for the product	<ul style="list-style-type: none"> • Understanding FDA device classification and requirements • Planning early for reimbursement coding and coverage
Component Testing	Design and conducting of tests to verify technology performance. Developing test procedures and defining performance metrics	<ul style="list-style-type: none"> • Pre-clinical testing for performance, safety and biocompatibility • Following good laboratory practices
Clinical / Comparative Effectiveness	Develop evidence to support technology safety and effectiveness as required for market approval, regulatory, and reimbursement strategy	<ul style="list-style-type: none"> • Understanding model systems • Optimizing clinical trial design for efficacy evidence

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Technology Development		
Technology Review	Evaluation of technology landscape to confirm product is feasible and novel	<ul style="list-style-type: none"> Objective evaluation of technology pros & cons
Concept Design	Creative design phase where early conceptual designs and schematics are explored	<ul style="list-style-type: none"> Emphasis on down-selection of features based on stakeholder needs
Product Requirements	Verified set of features and requirements that will serve as product development roadmap	<ul style="list-style-type: none"> Translating market requirements into product and technology requirements
Product Design	Technology design based upon product and market requirements	<ul style="list-style-type: none"> Verify product design via stakeholder review process
Prototyping	Development of a “looks like, feels like” version that can verify fit and function with stakeholders	<ul style="list-style-type: none"> Feasibility testing procedures to verify fit, form, and function
Design for Manufacturing	Scalable design of product for manufacturability within cost requirements	<ul style="list-style-type: none"> Optimization of materials, manufacturing, packaging, and labeling