The focus of the **AcexHealth Accelerator** is to develop and refine each of the key areas of your business plan to prepare you for execution of the plan in a time and capital efficient and effective manner, and to eliminate risk wherever possible. While oftentimes as entrepreneurs we believe we understand what needs to be done, another set of experienced external eyes that understand the demands and requirements of public and private funding sources, regulatory bodies, and purchasers across the healthcare spectrum can bring incredible value to your company.

The inherent risks associated with the development and commercialization of technological innovation in healthcare, combined with the implicit complexity of the technology transfer and regulatory processes, increases the uncertainty of any planning exercise.

How do we learn enough about alternative pathways to analyze and evaluate what strategies to choose in order to focus, considering that each strategy decision may eliminate other possible strategies?

In **AcexHealth** the selected companies will develop, refine and test their development, regulatory and go to market strategy in relation to their **Indication for Use and Market Claims**. Selected companies will complete Step 0, a Strategic Self-Assessment (Initial Evaluation) using the following table to conduct a structured analysis of the modules they believe will be most important for developing their business plan, and propose them for their pathway in the **AcexHealth** Program:

| | | |
|---|---|---|
| 1 | **Market Analysis, Competitive Positioning & Proof of Concept results** | **Identify the source of the opportunity (clear and broadly acknowledged unmet medical need). Develop a differentiated Value Proposition. Define the indication and claims and market opportunity size. Validate your hypothesis. Evaluate your study results to date and the level to which the results are supportive as proof-of-concept data for the value proposition, indication for use and market claims you previously developed.** |
| 2 | **Intellectual Property** | **Clarify your IP position and strategy for protecting the technology for the indication you are pursuing.** |
| 3 | **Regulatory Strategy & Development plan** | **Clarify your regulatory requirements and strategy based on the indication and desired claims and commercial considerations. Convert uncertainties into strategies, tasks and milestones! Develop the overall plan and timeline for the development of your product or service.** |
| 4 | **Internal & External Team** | **Profile the short-term human resource needs and how you will fill the critical roles (Internal or external resources).** |
| 5 | **Business and financial plan, Funding and Pitching** | **Develop business and revenue models appropriate for your product and the target customer. Prepare financial projections and cash requirements and identify sources that will be pursued, private and/or public. Develop a Concise, Powerful Pitch & Financials for raising capital or soliciting grants. Present information in a simple, understandable form for an investor or grant evaluator.** |

Selected companies will develop a consensus with the Support Program Committee on what are the necessary modules to accelerate the project and what the acceleration milestones will consist of.

Through a “Pick & Choose” methodology, participants receive one-to-one training and assistance on the key elements of the development and commercialization process of a health technology company.

In order to maximize the value that companies receive from the program, it is important that participants set aside time between meetings with the mentors in each module to work on developing the strategies and plans and incorporating the feedback and direction from mentors towards the next mentoring session. The

specific amount of time will depend on how advanced each company is in the development of the strategies and plans in each module.

**1.** The selected companies participating in the **Market Analysis, Competitive Positioning & Proof of Concept Results** module will focus on the following topics. The specific topics listed below are critical to understand in order to develop plans and strategies as all other aspects are dependent on these topics, as well as being critical to raising capital.

| | | |
|---|---|---|
| 1 | Market Analysis, Competitive Positioning & Proof of Concept results | 1.1. Current unmet medical need (Medical and or economic)<br>1.2. Indication for use. Market claims (Medical and or economic). Who is the user, who is the patient, who is the payer?<br>1.3. Determination of the market size TAM and SAM (serviceable available market)*<br>1.4. Project the market value (price) of the product (market value) based on target indication and claims<br>1.5. Alignment between who realizes the economic benefit and who is the payer<br>1.6. Value proposition-differential from competitors<br>1.7. Complete list and description of studies carried out to date<br>1.8. Main results obtained and conclusion analysis<br>• Do these studies provide proof of concept for your indication statement?<br>1.9. Studies to be conducted in the future |

In this module, the selected companies will:

- Identify the current unmet clinical need on which the company focused and its economic impact.
- Identify supportive documents establishing that it is a known and accepted unmet need in the clinical or payer environments.
- Is a pivot required?
- Develop the Indication for Use statement for their final product/service and the market claims that the product will support.
- Develop market size estimations based on bottom-up analysis whenever possible (highly preferred by investors), or top down otherwise.
- Develop the pharmacoeconomic concept: who receives the economic value; who is the payer; are they aligned.
- Develop an initial value proposition that is differentiated from current solutions, and solutions that are in development, that covers social, economic and clinical value as appropriate. Focused on value, not features and benefits.
- Validate that you have established proof of principle for the indication statement and claims you are pushing OR develop a plan for the studies required to establish proof of principle.

**2.** Companies participating in the **Intellectual Property** module will assess their current IP position and develop an IP strategy to protect their position as well as what impact other patents may have on their ability to commercialize the technology.

| | | |
|---|---|---|
| 2 | Intellectual Property | 2.1. List of filed patents to date and where they were filed<br>2.2. Initial analysis of freedom to operate (FTO)<br>2.3. Status of license agreements of institutions (Fit with Business Model) |

In this module, the selected companies will:

- Evaluate the best strategies for protecting the company's intellectual property, patents, trade secret,…
- Assess that the patents as filed are protective of the indication and claims developed in Module 1.

- Make an initial assessment of Freedom to Operate (FTO) and determine if there is a need for a more thorough FTO assessment through a patent attorney.
- Analyze in-license agreement, if applicable, or develop an in-license strategy to ensure that that license is compatible with the planned business model.
- Identify planned developments that may generate additional IP outside of the in-licensed IP.

**3.** Companies participating in the **Regulatory Strategy & Development Plan** module will assess options regarding regulatory strategy and develop an initial plan regarding the execution of that strategy.

| | | |
|---|---|---|
| **3** | **Regulatory Strategy & Development Plan** | **3.1. Regulatory strategy conditioned by the indication for use and market claims, Classification, Pathway, Predicate device**<br>**3.2. Regulatory framework for the current project (Normative Testing, preclinical and clinical testing).**<br>**3.3. Design requirements document. Based on Intended Use & Market Claims**<br>**3.4. List of all studies required for product development, analytic validation and clinical validation.**<br>**3.5. Gantt chart for the entire development process**<br>**3.6. Projection of associated costs** |

In this module, the selected companies will:

- Assess potential Regulatory Strategies
  - Targeted regions: Global, US & EU, China, …
  - Determine Classification – opportunities to enhance competitive position and/or commercial adoption through strategic adjustment of the indication and claims from Module 1 to impact classification.
  - Identify similarly classified technologies or products (Predicate for US)
- Identify regulatory pathway in targeted regions based on classification
- Develop initial plan for executing regulatory strategy
  - Required quality and regulatory resources and expertise
  - Design Controls
  - Quality Certifications
  - Normative testing requirements
  - Clinical data requirements defined by classification
- Develop a projected timeline and projected costs associated with regulatory
- Understand that a sound and thoughtful strategic regulatory plan is tightly coupled with the competitive positioning of a new technology, and it informs the sales and marketing approach, clinical strategy, quality processes, and risk management policies the company puts in place. The strategic regulatory plan should be considered early on and not be considered by itself.
- Develop the design requirements document, technical and market requirements, to which the development process will be managed.
- Establish design phases and design review points as per design controls or as applicable.
- Identify remaining development requirements
  - Product development
  - Product analytic validation
  - Product clinical validation – including pharmacoeconomic data and other data that may be required for reimbursement or to encourage clinical adoption of the company's technology.
- Assess the most time and capital efficient way to carry out these development processes. (Outsource, e.g. CRO, outsourced development and manufacturing or manage internally e.g. hire resources into the company to perform these activities)
- Develop Gantt chart for development process

**4.** Companies participating in the **Internal & External Team** module will assess, based on information developed in prior modules, what activities the company will perform using internal resources and or external resources in order to minimize time and cost and maximize commercial success.

| | | |
|---|---|---|
| **4** | **Internal & External Team** | **4.1. Existing team and initial roles**<br>**4.2. Complete job description for all roles needed in the near future critical hires**<br>**4.3. Profiles required for the Advisory Board** |

In this module, the selected companies will:

- Determine what activities the company wants to keep internal and what it wants to outsource.
- Understand the team's technical and business abilities. What capabilities does the company currently have?
- Identify gaps in internal resources and identify critical hires required to execute the company's strategy.
- Understand how and when to build a Scientific/Business Advisory Committee

**5.** Companies participating in the **Business and financial plan, Funding and Pitching** module will focus on defining the company's business model and preparing the documentation necessary to present the information from all the modules to investors and others outside the company, in a concise, clear and compelling way.

| | | |
|---|---|---|
| **5** | **Business and financial plan, Funding and Pitching** | **5.1. Definition of the company's business model / Revenue Model**<br>**5.2. Quantification of the overall cash requirements (cash flow) to milestone, and initial revenue projections.**<br>**5.3. Funding strategy (Dilutive & Non-dilutive)**<br>**5.4. Preparation of the Financial Plan: Cash Flow statement and Profit & Loss Statement**<br>**5.5. Risk analysis and mitigation plan**<br>**5.6. Preparation of the company's pitch deck**<br>**5.7. Valuation of the company and comparable (similar cases to support valuation, exit multiples for your market space etc.)**<br>**5.8. Timeline** |

In this module, the selected companies will:

- Understand the different types of business models that are typically utilized in the company's field (biotech, medtech or digital health), including their relative advantages and disadvantages.
- Use the work the company's has done in other steps to brainstorm an innovative model for the company's product or service considering the requirements of the customer as well as payers (reimbursement)
- Identify the most appropriate business/commercialization and revenue model as determined by the company´s: product; target market; target customer and targeted payer.
- Using the strategies and cost projections from other modules, e.g., regulatory, development…, project total costs through to a funding milestone, e.g., design freeze, analytical validation, regulatory approval, commercialization, …
- Develop a financial model and plan.
- Develop an initial risk assessment and mitigation strategies

- Consider the different types of funding including dilutive (Angel, VC) and non-dilutive funding, the stage at which they might be most appropriate, and how they are likely to affect the company and its investors.
- Prepare a clear, concise and compelling pitch deck to lead the investor to a conclusion that this is a great investment.
- Determine valuation of the company based on market factors and revenue projections and comparable investment transactions in the market space.
- Understand the criteria used by different investors to evaluate a business opportunity and the most critical points.
- Analyze similar cases to support valuation, exit multiples for company's market space etc.
- Identify the appropriate investor characteristics for the development stage of the company and the targeted market for the product or service.

Another significant benefit of the AcexHealth program is the opportunity to **interact with the Maryland/Washington D.C. or Boston life sciences ecosystem**, some of the strongest in the world. Teams have the chance to forge connections with these ecosystems* and pitch their projects to the investment community in the region**. The top five selected companies from the AcexHealth acceleration program will be selected based on the final pitch and will be invited to participate in the event in the USA.

* Thanks to TRADE. Business Agency for the Transformation and Economic Development. Ministry of Economy, Finance and European Funds (Regional Government of Andalusia).

MARYLAND/ WASHINGTON D.C./ BOSTON IMMERSION

When: **1st semester 2025**

Teams will travel to Maryland/Washington D.C or Boston to polish and give their pitch to these ecosystems, in order to improve their capabilities and expand their network.
Teams will also meet with stakeholders from these ecosystems in order to extend their customer validation.

Organizers:

Junta de Andalucía Consejería de Universidad, Investigación e Innovación · Junta de Andalucía Consejería de Salud y Consumo · Junta de Andalucía Consejería de Economía, Hacienda y Fondos Europeos · PTS Parque Tecnológico de la Salud · Universidad de Granada · Cámara Granada

Sponsors:

bida farma · vircell Microbiologists · kaudal