

New business models in Health Technologies

XPatient Barcelona Congress

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Who are we?



GENESIS Biomed is a consultancy firm in the biomedical healthcare sector specialized in providing consulting services to spin-off and start-up companies, entrepreneurs and research centers.

Based in our expertise we help entrepreneurs and researchers to shape their business plan and we support them in the private fundraising process. We have raised more than 40 M€ in the last 4 years.

Our expertise domains are biopharmaceutical, biotechnological, medical devices, in vitro diagnostic, nutraceutical and cosmetic.

With more than 20 years of expertise in the healthcare sector, we are born in May 2017 and we are located in the Barcelona Science Park.

In addition, the company owns GENESIS Ventures, a new fund sized in 1,2 M€ that invests in early stage research projects in the biomedical field, with the aim to accelerate their development and reach key value milestones to found the company and attract a first round of investment from other venture funds.

Our locations: Barcelona and Madrid

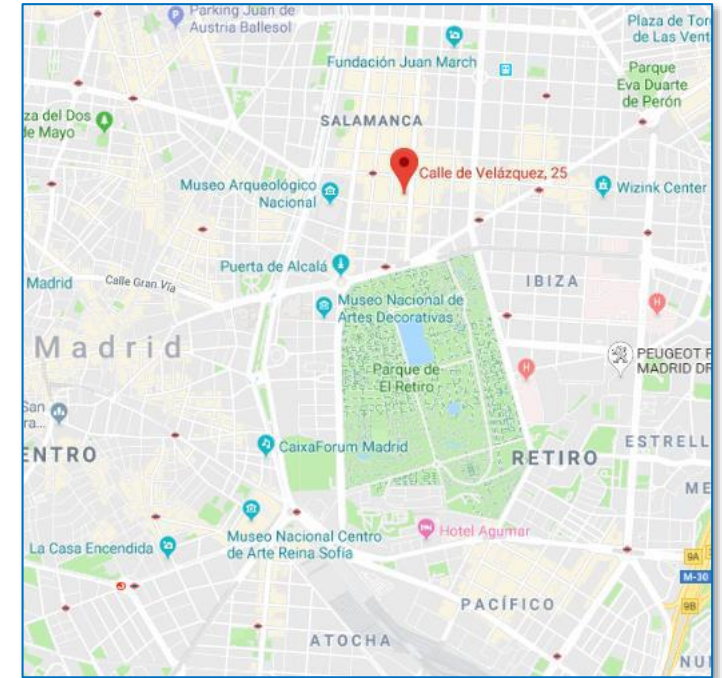
We are glad to announce that in September 2019 we will open our new offices located at Velázquez 25, Madrid.

Located in the real center of Madrid, our new offices will allow us to work closely with the clients we have in Madrid area.

A new Office Manager will be leading Madrid Office. We are currently in the selection process of this new member of our staff.

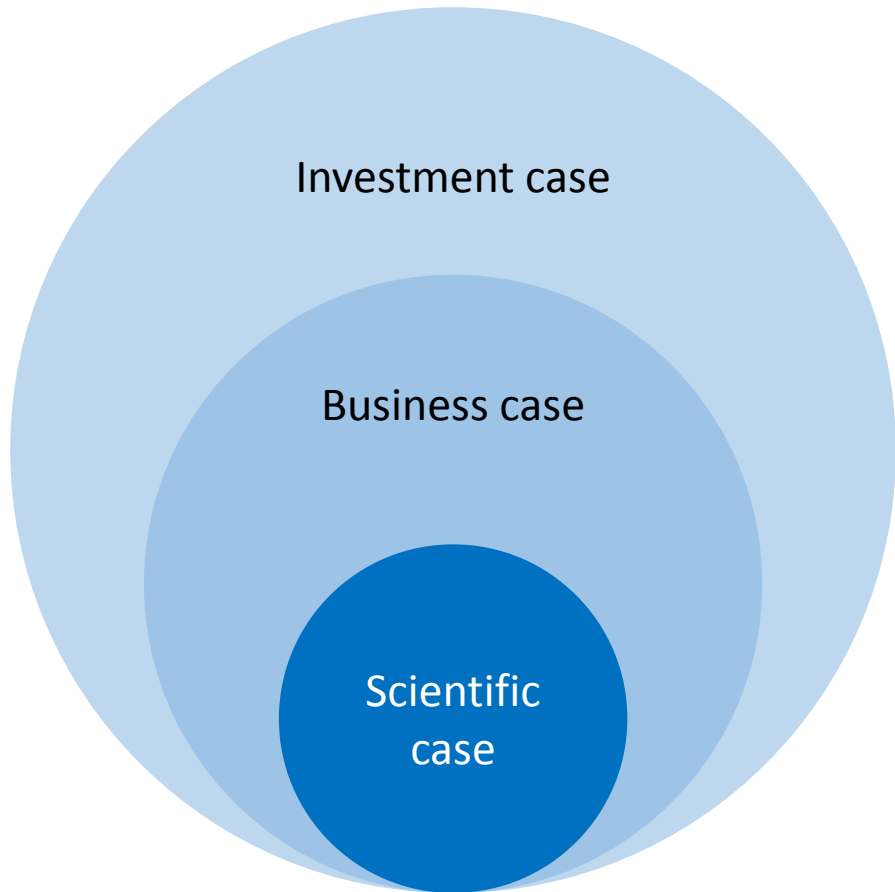


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Baldiri Reixac 4
08028 Barcelona



Madrid Office
Calle de Velázquez 25, 2º A
28001 Madrid

Our value proposition in fundraising projects: from the Scientific case to the Investment case



In the projects related to fundraising, we always start from the **Scientific Case**, always excellent that comes from the Research Group.

We convert it into a **Business Case**, that is containing all the aspects to be considered in a Business Plan.

Finally, creating a team between GENESIS Biomed and the Research Group, we start a process that helps the investors to create their **Investment case** that provides them support in the decision making.

Our success stories in fundraising



- Medtech project: stratification of patients suffering from atrial fibrillation
- 1 M€ raised in January 2019
- Investors: Family offices and EU funds



- Pharma project: new aptamer for ischemic stroke
- 2,7 M€ raised in May 2017
- Investors: Caixa Capital Risc and Inveready



- Medtech project: new catheter for thrombectomy
- 15 M€ raised in May 2017
- Investors: Ysios, Omega, Innogest, Banc Sabadell



- Biotech project: recombinant protein for NSCLC and TNBC
- 4,2 M€ raised in July 2017
- Investors: ALTA Life Sciences and Healthequity



- IVD project: new biomarker for cardiovascular ischemia
- 2,4 M€ raised in October 2017
- Investors: Caixa Capital Risc and Healthequity

Participation in EU projects as proactive partners



- 1 Preparation of Business Plan
- 2 Market research and market analysis including fieldwork
- 3 Implantation Plan and Market Access Plan
- 4 Commercialization and Exploitation Plan
- 5 Regulatory roadmap and Regulatory development activities
- 6 Business Development for Licensing / M&A

Currently working in 7 funded projects. We become very proactive partners in the preparation of the proposal and in the hearings. We are also a high proactive business partner during the development of the project.

GENESIS team: 9 committed people and accumulated experience of >60 years

Josep Lluís Falcó Founder & CEO	Natalia de la Figuera COO	Jordi Ortiz Senior Consultant	Carles Taulé Consultant	Berta Borràs Consultant	Mireia Samitier Consultant	Gisela Gallego Consultant	Josep Maria Balaguer Consultant	Anna Miró Consultant
Chemist PhD, MBA	Chemist PhD, PMP®	Chemist	Pharmacist	Biotechnologist Biochemist	Biologist	Biotechnologist	Biomechanical engineer	Biomedical Sciences

Our Scientific Advisory Board



Dr. Josep Tabernero
Chairman of the Board – Expert in Oncology

Head of the Department of Medical Oncology in Vall d’Hebrón University Hospital; Director of the Vall d’Hebrón Research Institute in Oncology.



Dr. Pere Ginés
Expert in Hepatology

Chairman of Liver Unit, Hospital Clinic Barcelona; Full Professor of Medicine, University of Barcelona; Director of Liver Transplantation; Head of Research Group, IDIBAPS and CIBEReHD.



Dr. Rafael Cantón
Expert in Infectious Diseases

Head of the Clinical Microbiology Department at the University Hospital Ramón y Cajal; associated Professor of Clinical Microbiology at Complutense University of Madrid.



Dr. José Luís Molinuevo
Expert in Neurology

Scientific director and Head of the Clinical, Biomarker and Risk Factors Research Group at the Barcelonabeta Research Centre (BBRC); associate professor in University Pompeu Fabra.



Dr. Francisco Fernández Avilés
Expert in Cardiology

Full Professor of Cardiovascular Medicine at the Complutense University (UCM); Chairman of the Department of Cardiology in the University Hospital Gregorio Marañón of Madrid; Scientific Director of the Spanish Network Centre for Cardiovascular Research (CIBERCV).



Dr. Rafael Simó
Expert in Endocrinology

Chair of the Division of Endocrinology and Nutrition at Vall d’Hebrón University Hospital; Director of Diabetes and Metabolism Research Unit at Vall d’Hebrón Research Institute (VHIR); Professor of Medicine & Endocrinology at the Autonomous University of Barcelona.

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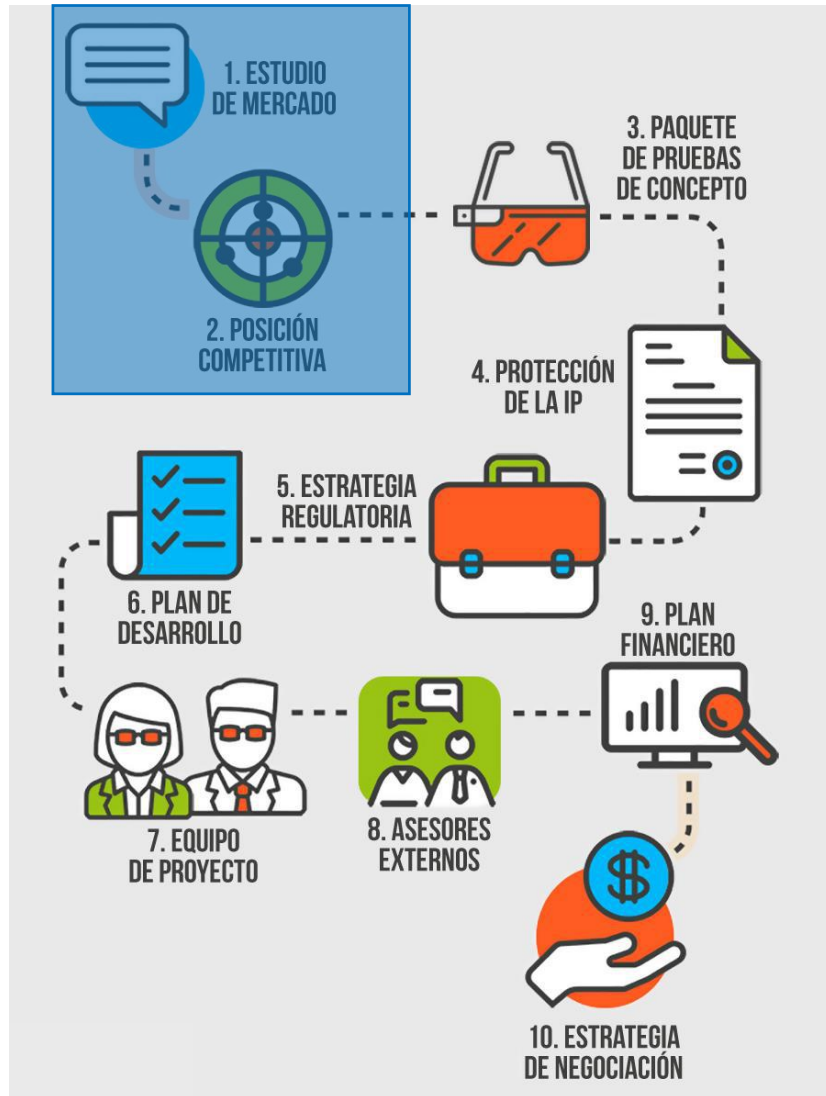
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Main topics to take into Account to be able to reach the market



Our **Methodology**. Which are the 10 success factors to learn and implement? (1/5)



1. Market Analysis

- Current unmet medical need
- Epidemiology
- Determination of market size
- Description of market trends
- Analysis of main players in the market (commercial products)
- Description of the future competitors (development projects)



2. Competitive positioning

- Analysis of main features of current and future competitors
- Price analysis
- Business model analysis
- Market share analysis
- Voice of Customer and Cost-effectiveness analysis
- Competitors matrix

Our **Methodology**. Which are the 10 success factors to learn and implement? (2/5)



3. Proof of Concept results

- Complete list and description of studies done till date
- Main results obtained and conclusion analysis
- Studies to be conducted in the future
- Current agreement with the Main Institution
- Outsourced studies and external collaborations
- R+D Gantt chart



4. Intellectual Property

- List of filed patents till date
- Analysis of the current situation of each filed patent
- List of potential future patents in the project
- Freedom to operate analysis
- License Agreement from the Institutions
- IP strategy of the company

Our **Methodology**. Which are the 10 success factors to learn and implement? (3/5)



5. Regulatory Strategy

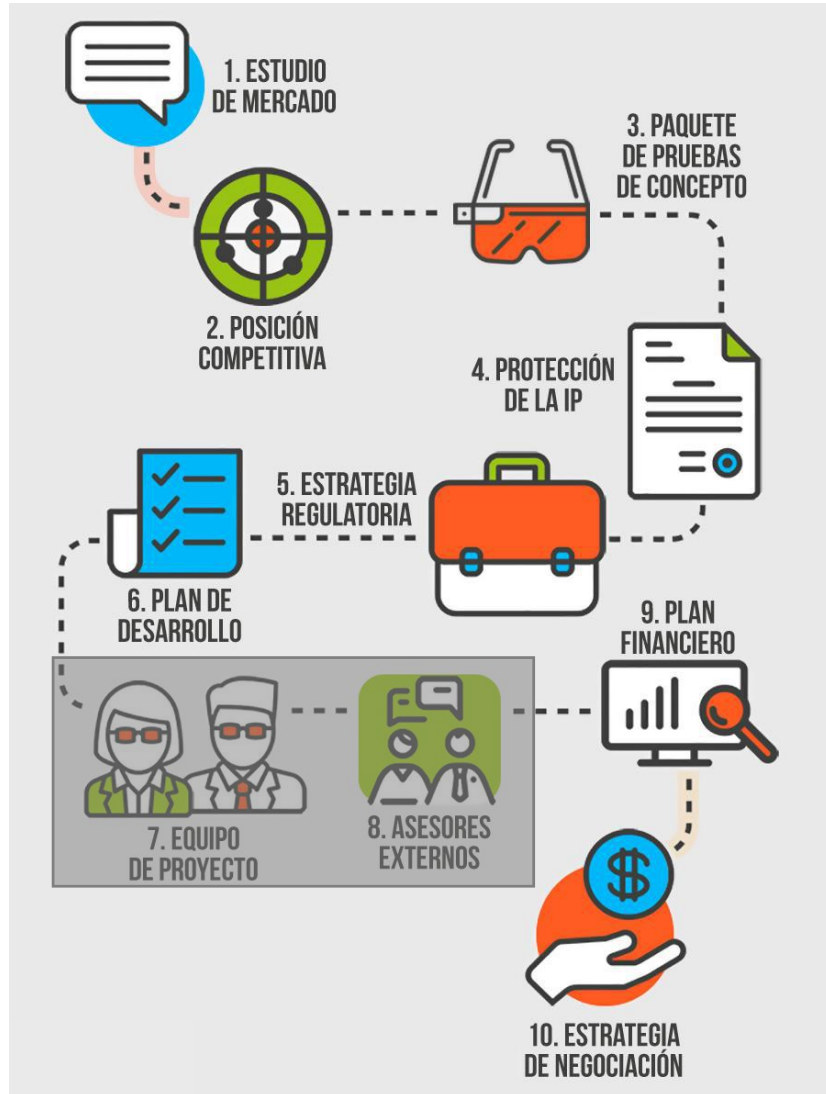
- Regulatory framework for the current project
- Analysis of the corresponding guidelines and directives
- Current regulatory considerations
- Future trends and regulatory changes
- Regulatory strategy and validation
- Regulatory roadmap



6. Development plan

- List of all needed studies for the development of the product
- Gantt chart for the whole development process
- Identification of main milestones
- Measurement of timelines
- Identification of potential outsourced partners
- Prediction of associated costs

Our **Methodology**. Which are the 10 success factors to learn and implement? (4/5)



7. Internal team of de company

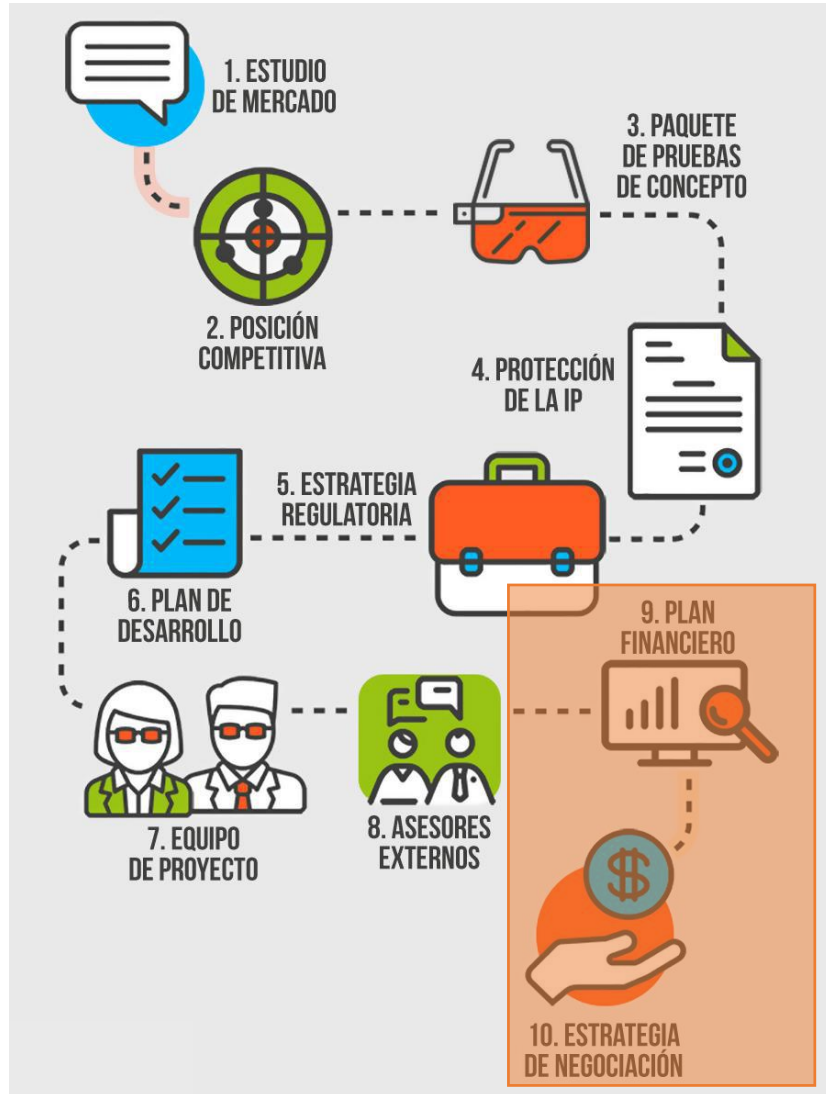
- Existing team and initial roles
- Presence of a full-time CEO
- Complete job description for all needed roles in the future
- Organigram analysis and Headcount evolution in the company
- Analysis of salaries and ESOP for internal staff
- Partners Agreement, Governance and Reserved matters



8. External team

- Profiles needed for the Scientific Advisory Board
- Design of the Board of Directors
- Identification of the Chairman
- Identification of suitable outsourced roles and service providers
- Analysis of costs and quotations
- Design of ESOP for key external people

Our **Methodology**. Which are the 10 success factors to learn and implement? (5/5)



9. Financial Plan

- **Definition of the Business Model of the company**
- Quantification of the global cash need
- Main financial milestones and Identification of Tranches
- Fundraising strategy for Investors and Exit scenario analysis
- Valuation of the company and Cap Table analysis
- Preparation of the Financial Plan: CF, P&L and BS



10. Strategy and Fundraising negotiation

- Selection of the most suitable investors
- Preparation of the slide deck of the company
- Roadshow and first meetings round
- Building the syndicate up
- Analysis and negotiation of the Term sheet
- Preparation of Data room for Due diligence
- Negotiation of the Investment Agreement and Partners Agreement
- Closing of the Round

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Hardware-as-a-service (HaaS)

Giving access to hardware along with accompanying software, maintenance, installation, and upgrades. Customers pay for the value provided by the service, rather than the underlying hardware.



Company



Customer

Payment for a period of time and for the software they are using.

Access to hardware accompanied with software

Implications:

- Proactive service model
- It may not fit all hardware products (too cheap or too expensive)



Subscription or Pay-per-use

Valuable to Business

Benefits

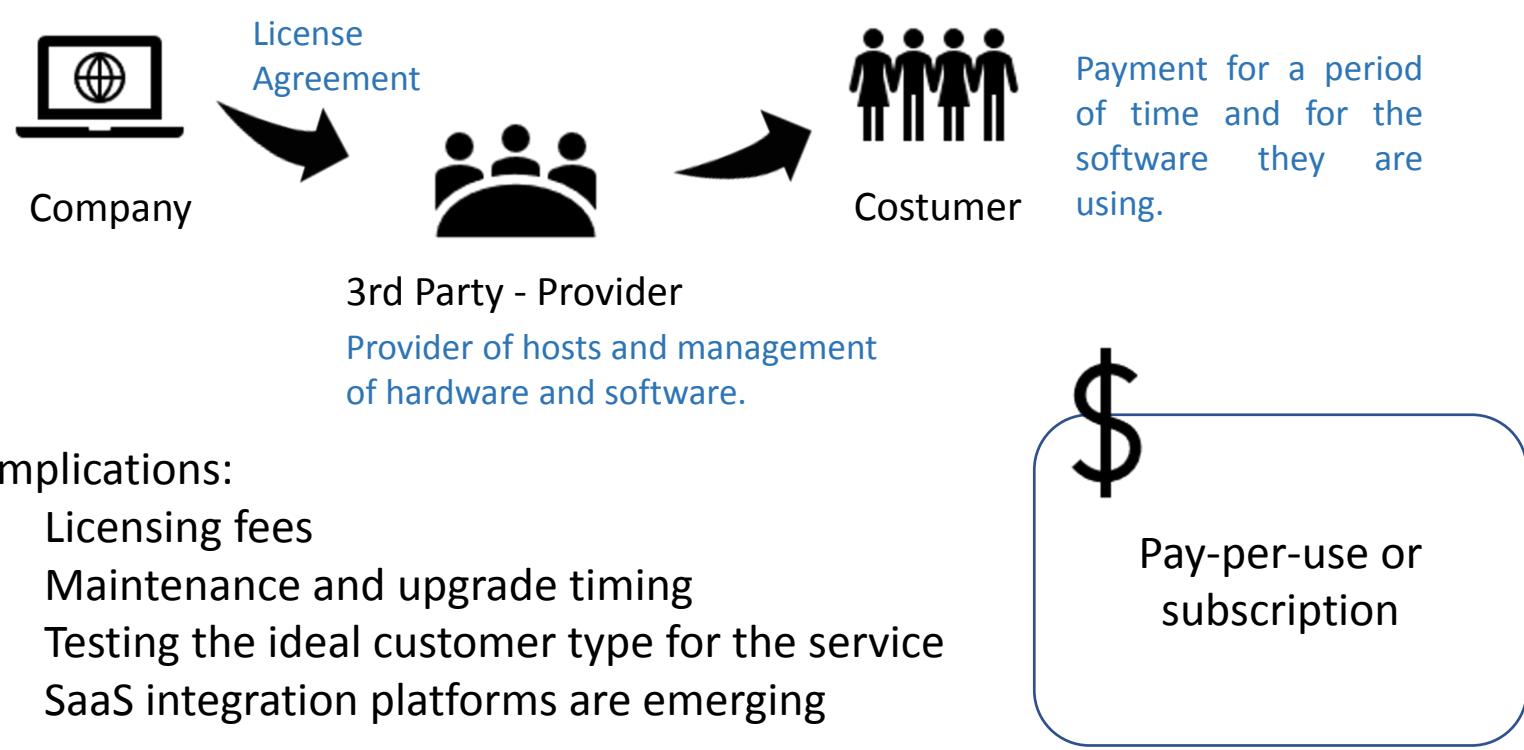
- Accelerates growth by lowering barrier to purchase
- High margins for business overtime with profits built into recurring revenue and usage
- More difficult to customers to displace

Challenges

- Often requires complete reconfiguration of the value proposition
- Difficult unit economics at scale

Software-as-a-service (SaaS)

Software is licensed and centrally hosted available through digital interface (app, device, etc.).



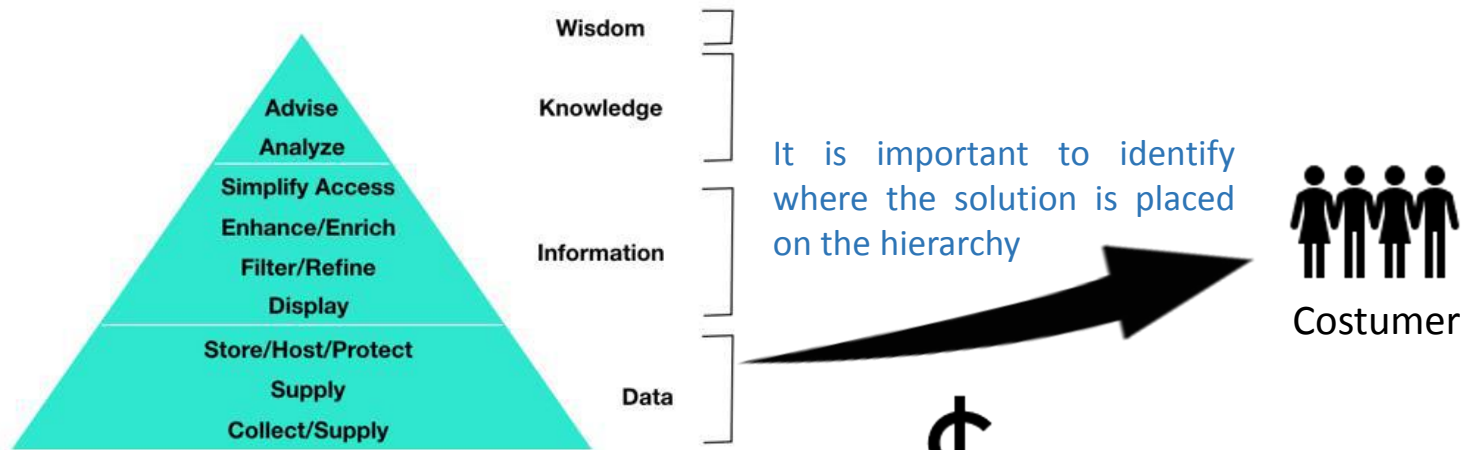
Implications:

- Licensing fees
- Maintenance and upgrade timing
- Testing the ideal customer type for the service
- SaaS integration platforms are emerging

Valuable to Business
Benefits
Lower costs compared to the traditional model (install & configure the app)
“Click to ship” vs. costly installs
No need for multiple versions of the software
Challenges
Need of a two-step value proposition (1 for user and 1 for provider)

Data-as-a-service (DaaS)

Data management as a core underlying asset; services are created on top of data that is collected, trained, and labelled.



Implications:

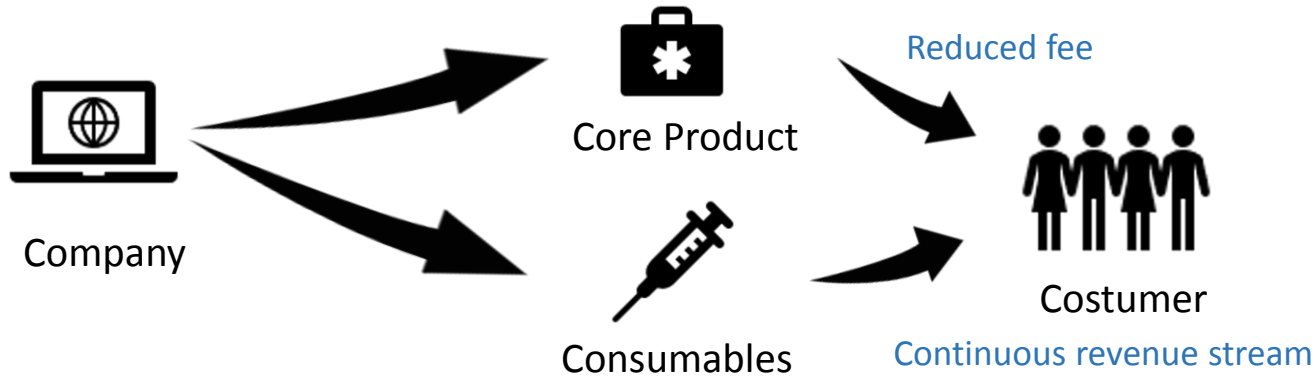
- Build moats around the data
- Continuum exploitation of data
- Opportunities for data to predict future outcomes

\$ Two different pricing models:
1. Volume based
2. Data type based

Valuable to Business
Benefits
Potential value if hard-to-access data is reached
Value in structured and cleaned data
Data as a driver for customer and company value
Challenges
Security issues and user privacy
Cost of data operations

“Razor & Razorblade” or “Nespresso”

Designed to encourage price of consumption over time. The core product is priced for sale and uptake, while the real money is made on the consumable.



Implications:

- Typically a late stage strategy
- Customers value a proprietary system
- Turning the purchase of the consumables into a habit

\$

A reduced upfront fee for the core product and a continuous purchasing of the consumables

Valuable to Business

Benefits

- Accelerated growth by lowering the purchase barrier
- Service models to lock-in customers
- High margins for business overtime

Challenges

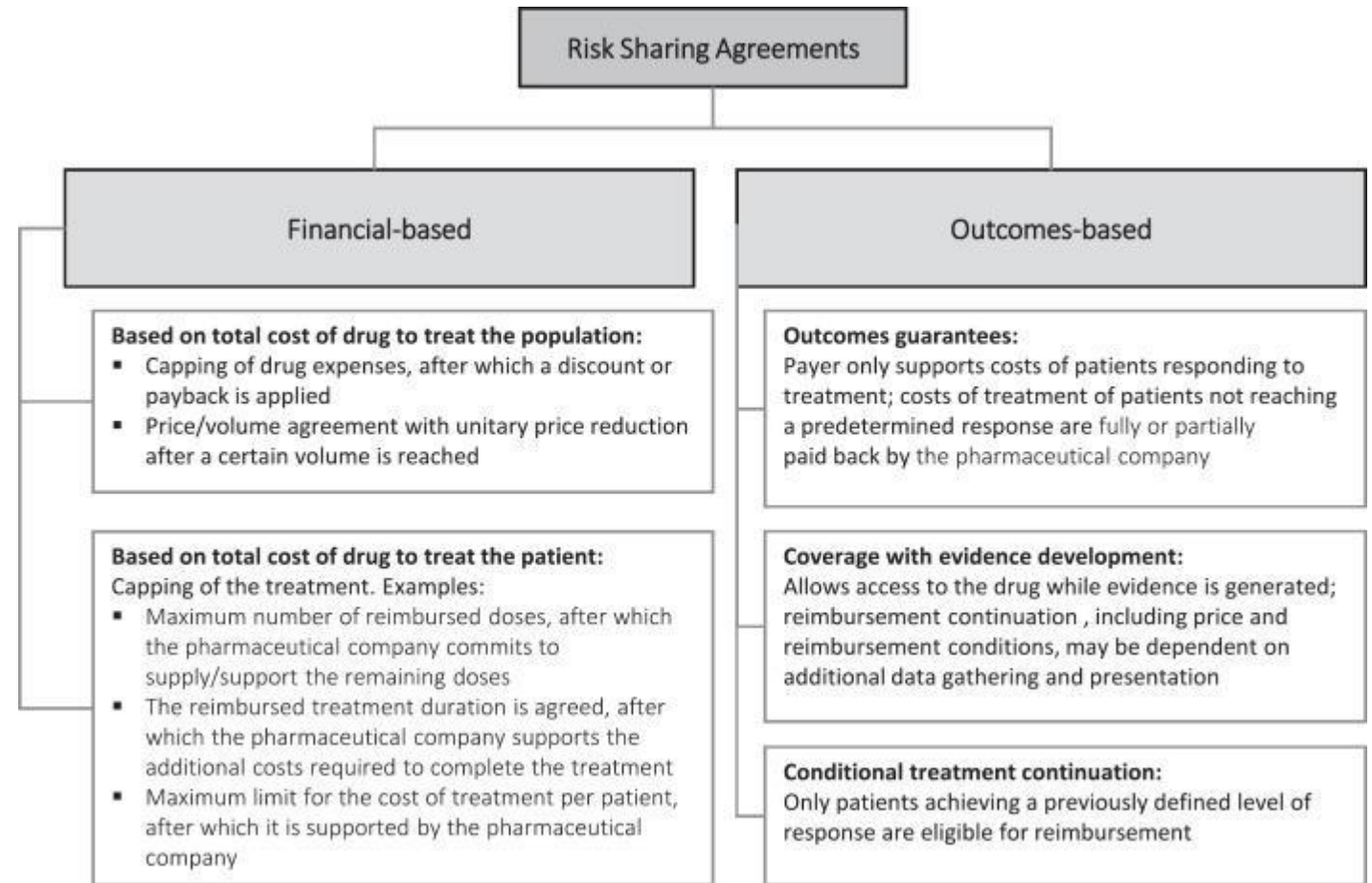
- Suppliers may create off-brand products (importance of IP)
- Customers may complain of product lock-in

Risk-sharing agreements (RSA)

According to Gonçalves et al. this concept is recent in the health sector. They support that RSA are divided into financial agreements and clinical results agreements.

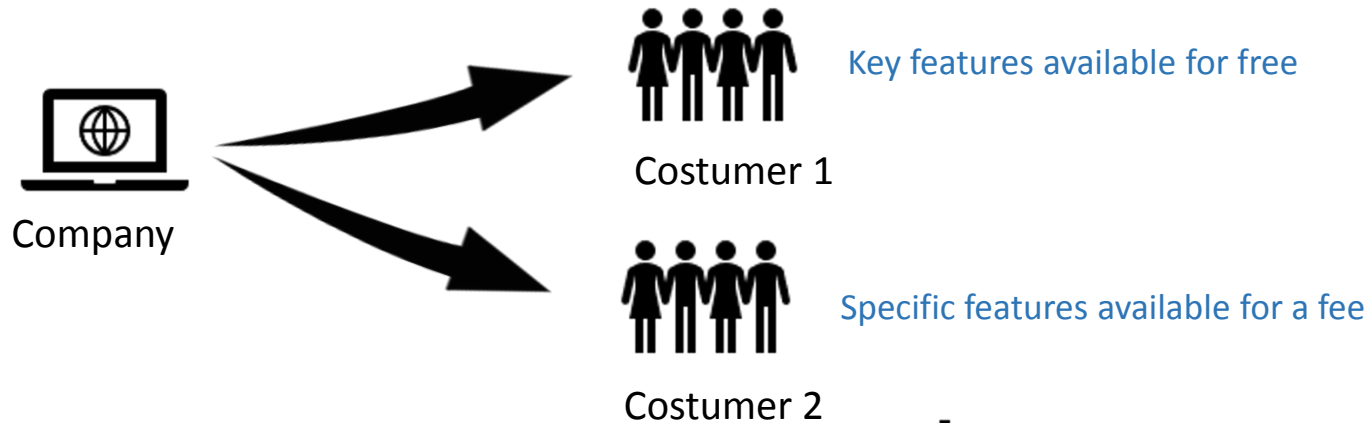
RSA allows:

- Mitigation of uncertainty about clinical outcomes and cost-effectiveness.
- In clinical practice, reimbursement or payment of the drug can be based on the performance.
- Establishing an optimum sub-population of patients to use the product according to selection criteria.
- Managing the budgetary impact.
- Building confidence between with payers.



Freemium Service

Customers are able to use some key features for free whereas there are other specific features and services delivered for a fee.



Implications:

- Cost of acquiring free users (marketing)
- Conversion from free to pay
- Other competitors with services for free
- Need for other revenue streams to generate earnings



Some options are available for free and key features for a fee (subscription)

Valuable to Business

Benefits

Faster potential growth (viral adoption)

Opportunity to learn from free users (identify behaviors)

Challenges

Stablishing de right balance between free and premium

Two step value proposition: one for the free user and for the paying user

Sales department is required

Advertising-Supported

A company that has an audience for creating content/service sells access to advertisers.



Implications:

- Low entry barrier but difficult to make revenue
- Trust issues



Advertisers pay a fee for its advert.

Valuable to Business
Benefits
Profitable when the selling process is automated
Challenges
Data privacy
Advertising is a discussed business model
Changes in regulatory may affect the cost structure of the company
Investors avoid new digital advertising properties

Examples





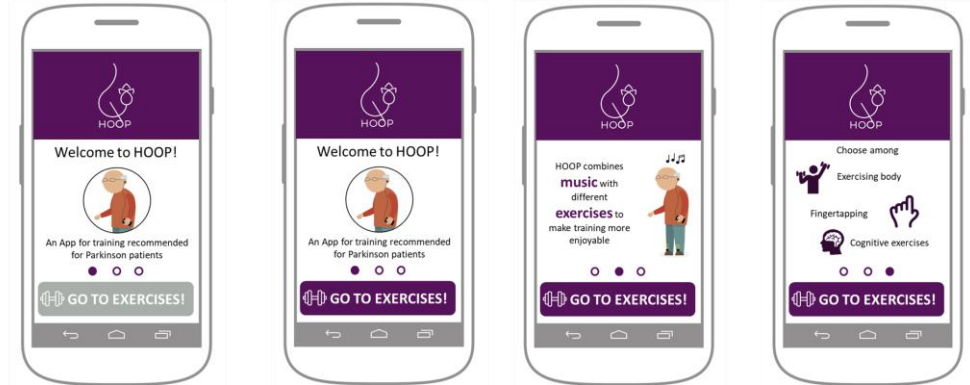
The Product:

Rehabilitation system which combines physical exercises based in musicotherapy and External Rhythmic Cueing (ERC) to improve clinical outcomes in Parkinson progression.

Contains:

- Sensors: To evaluate together with the App the performance of the patient doing the exercise.
- App (HOOP Mobile): Intuitive and easy app which shows the patient how to perform the exercises.
- HOOP Web: To help therapists doing the follow-up of their patients and recommending most suitable exercises.

1ª vez (primer uso): botón desactivado Resto: botón activado desde el inicio



BUSINESS MODELS

1. At home rehabilitation → Freemium Service & Subscription (monthly)
2. e-Consultation → Pay-per-use / consultation
3. Advertising supported

ADmit – In Vitro Diagnostic (IVD) Test

The Product:

IVD Test to analyze the methylation profile of mtDNA obtained from blood samples in order to diagnose Alzheimer's disease in early stages.

Biomarkers are analyzed with next generation sequencing techniques and afterwards ADmit Therapeutics uses its software to detect the disease depending on the methylcytosines profile.

Contains:

- Software which analyses the methylcytosines profile and gives a diagnose of Alzheimer Disease.
- Next generation sequencing equipment

BUSINESS MODELS

1. Pay-per-use: ADmit provides the results of the test to CROs and pharmaceutical companies. Results are obtained in a central lab where ADmit Therapeutics manages all the process.
2. Software-as-a-service: ADmit licenses its software to another company which will exploit it in order to obtain the results from the test and detect or not the presence of Alzheimer.

Walk Test+ – MedTech

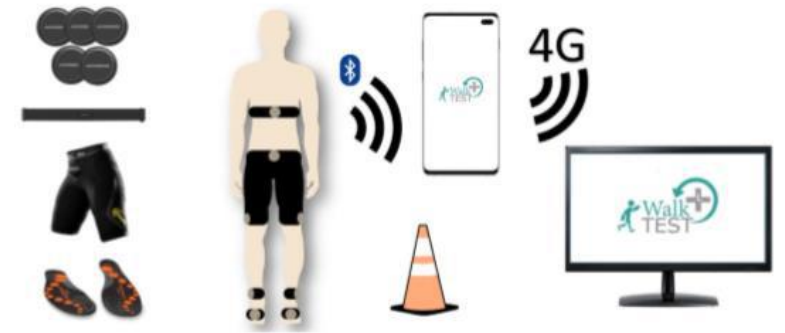
The Product:

The Walk Test + is a wearable device developed to be used during the performance of the 6 minutes walking test (6MWT) with the aim of testing patient's capabilities in a more objective manner.

The test measures the distance walked in 6 minutes and provides data about the response of the cardiopulmonary and musculoskeletal systems involved in the exercise.

Contains:

- Software: it consists on an app, the back-office website and the data platform which allow controlling, setting and downloading the parameters and the results obtained.
- Wearable sensors: an accelerometer, a gyroscope, an electromyogram, an oximeter and a spO2 from different companies to analyze the parameters of interest.



BUSINESS MODELS

1. HaaS. Hospitals pay an initial subscription and pay per every use.
2. DaaS. Consultancy services with generated data.

CORIFY – MedTech

The Product:

Technology consisting of an innovating imaging system capable of processing a high-density group of electrodes in order to select the most appropriate treatment strategy in patients with atrial fibrillation.

Contains:

- Software and device for 3D bed scan geometry reconstruction and integration of the results.
- ECGi electrodes: disposable placed on the patient's body to obtain a reconstruction.



BUSINESS MODELS

1. Nespresso: the hospital obtains the software and the device needed for a fee and pays for each disposable needed for every patient.
2. HaaS if subscription costs are not zero.
3. The hospital could obtain the hardware and software by renting or with the pay-per-use model.



Thank you for your attention

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