

Lecture #3

Market

Aims:

- Go through an example case study on Theranos
- Get an idea on HOW to get market and competitor data for your innovation

Course content and schedule 2024

Lecture #/Date	Topic	Details	Seminar tasks
1/ 12.09	General Introduction	Aims of the course, expectations, tasks and assessments General proceeding	Watch Elisabeth Holmes Documentary (Theranos story)
2/ 19.09	Roadmap from academic idea to startup	template business example, Learn about all the steps needed to translate a scientific idea into a startup and what your pitch deck should include => Focus on Value proposition and Business model	Define customer value proposition, USPs and business model (= business example) of Theranos Grouping and assignment of individual presentations
3/ 26.09	Market analysis	Market size, competitors, customer models, growth and scalability,	Introduction into GlobalData, Find market data on your business example & group innovation
4/ 03.10	Corporate planning	Business models, exit strategies, website & visibility,	Define business example of your group innovation, define markets and competitors
5/ 10.10	Business examples	Business examples 1-4 , detailed feedback	
6/ 17.10	Intellectual property and other legal issues	Business examples 5-8 Patents – facts, data bases, examples Concept of freedom to operate, regulatory hurdles, etc.	Find & analyze patents in your field
24.10 – no lecture!			
7/ 31.10	Timelines & initial steps	Business examples 9-12 Milestones and finance plan from idea to startup/product	Prepare milestones and financial plan for your startup idea
8/ 07.11	Finalizing the pitch deck	Business examples 13-16 Recap: Detailed analysis of individual case studies, last year’s best group pitch and TheraMe pitch	Finalize pitch deck
9/ 14.11	How to secure funding	Business examples 17-20 Public funding programs, investments, venture capital, EPFL programs	
11/ 21.11	Guest speaker Daniel Alpern (EPFL entrepreneur)	Business examples 21-24 Introducing Catlyze4Life	Prepare Executive Summary and commercial potential in C4Lformat
12/ 28.11	Guest speakers Gautam Maitra (EPFL C4L)	Introducing EPFL Launchpad Initiative	
13/ 05.12	Pitches Groups A (e.g. 4-6) Feedback Groups B (e.g. 1-3)	10min pitches with non-presenting students to provide written feedback, Submission of Executive Summary and commercial potential in C4Lformat	Prepare written feedback on other group’s pitches
14/ 12.12	Pitches Groups B (e.g. 1-3) Feedback Groups A (e.g. 4-6)	10min pitches with non-presenting students to provide written feedback, Submission of Executive Summary and commercial potential in C4Lformat	
15/ 19.12	Trophy Award & Feedback		

Prepare your own case study

(first presentations in 2 weeks from now!)

- **Problem 1-2 slides**
- **Solution and USP 1-2 slides**
- **Business model 1-2 Slides**
- **No market data – this is a requirement only for the group pitch**

Previous **individual case studies** included:

CARBIOS – Enzymes powering the circular economy (Moodle)

ALGENOL – harnessing the sun to fuel the world (Moodle – failed startup)

Recap from last week

Example case study on theranos:

- **Problem 1-2 slides**
- **Solution and USP 1-2 slides**
- **Business model 1-2 Slides**

Groups & example innovations

Previous (hypothetical) **group innovations** included:

REDinal – epi-retinal implants to restore vision (Moodle)

Limitation: 2-year lifespan, surgical intervention required

Breath analyzer for early detection of cancer

Limitation: Not able to discriminate cancer types and stages

RoboDoc: Robot assisting medical diagnosis

Limitation: No human interaction, no invasive procedures

TheraMe! example:

Invention/USPs	Limitations	Other points
Microfluidic drug testing on tumor biopsies	Patient benefit not yet shown	TRL IP Costs Technology*

* Combination of droplet microfluidics with microfluidic valves using proprietary technology

Defining your market

Commercialization

1. What is the **USP**? Is there a **market** and how big is it?
2. How do I address my **customers**, what is the **business model**, is it **scalable**?
3. What is needed (**time, budget and resources**) to develop a minimal marketable product (**MMP**)?
4. Do I have **patent protection** and **freedom to operate**? Any other **legal or regulatory hurdles**?
5. How to secure **funding**?

The total economic cost of cancer is 1.14 trillion US\$/year

Annual sales in the field of cancer diagnostics are 160 billion US\$/year

Annual sales of cancer diagnostics in Switzerland are ??? US\$/year

Pancreatic cancer accounts for only about 3% of all cancers



How do I get MY market potential out of all these numbers and infos?

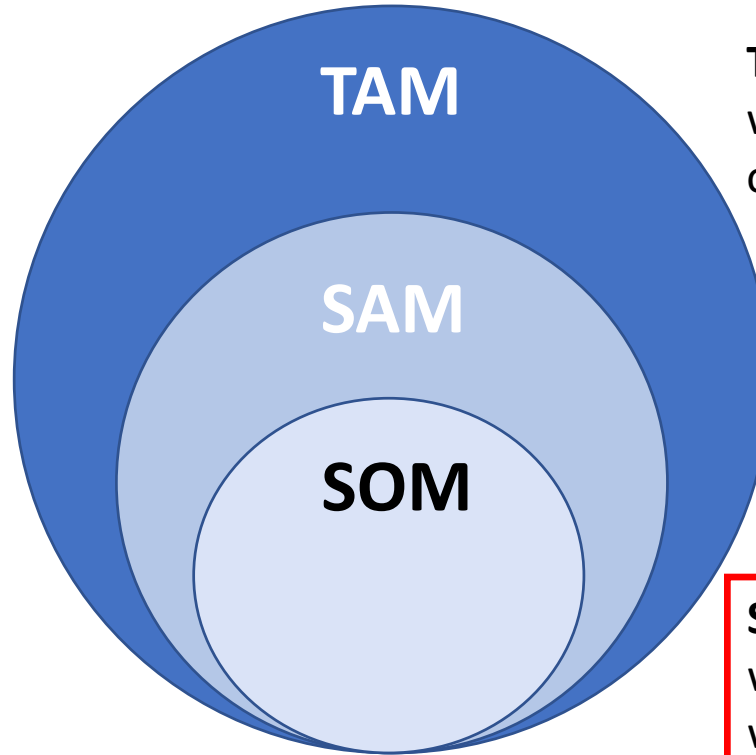
=> Today's lecture on market analysis and intro to GlobalData

How would YOU calculate the market for diagnostics/assays for personalized colorectal cancer therapy?



Total global market $\neq$ your market

SAM = Serviceable Addressable Market, e.g. portion of the TAM that can finally be acquired based on your business model (e.g. a specific market share in specific countries for specific indications)



TAM = Total Addressable Market, e.g. worldwide market for in vitro diagnostics in oncology, assuming a 100% market share

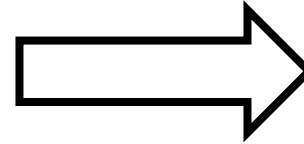
SOM = Serviceable obtainable market, e.g. what you can realistically capture and serve with your resources

Desired market data

Case study TheraMe!

www.besttherapyforme.com

Invention/USPs	Limitations	Other points
Microfluidic drug testing on tumor biopsies	Patient benefit not yet shown	TRL IP Costs Technology*



* Combination of droplet microfluidics with microfluidic valves using proprietary technology

- a) **Worldwide market size & growth** (what is the ultimate commercial potential of your product)?
- b) **Size of initial market niche** (initial commercial potential)?
- c) Worldwide **competitor sales**, total sales in your initial market niche, market share of #1 competitor (what sales can be expected)?
- d) What is the **market value of your competitor** (what future value of the company can be expected)?

Worldwide market size and growth in the field of cancer diagnostics

Hits when using ["cancer diagnostics" market] as a search term in Google:

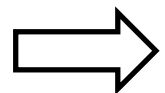
The global cancer diagnostics market is expected to grow from \$156.27 billion in 2020 to \$170.21 billion in 2021 at a compound annual growth rate (CAGR) of 8.9%. (ReportLinker)

The global cancer diagnostics market size was valued at USD 144. 4 billion in 2018 and is expected to register a CAGR of 7.0% over the forecast period. (Grand View Research)

Market size: USD 163.84 Billion in 2020, Market Growth: CAGR of 6.3%, Market Trends: Increasing number of private diagnostic laboratories (Reports and Data)

The global Cancer Diagnostics Market was pegged at \$168.60 billion in 2020, and is estimated to reach \$280.59 billion by 2028, growing at a CAGR of 6.9% from 2020 to 2028. (Allied Market Research)

Can be complemented by searches on professional data bases on business numbers such as **Global Data, Statista, Crunch Base**



Worldwide market size & growth ≈ USD 160 billion per year, 7% CAGR

Definition of CAGR

(modified from Wikipedia)

Compound Annual Growth Rate (CAGR) is defined as:

$$\text{CAGR}(t_0, t_n) = \left(\frac{V(t_n)}{V(t_0)} \right)^{\frac{1}{t_n - t_0}} - 1$$

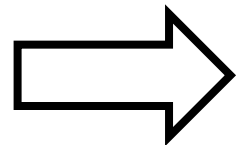
where t_0 is the initial value, t_n is the end value, and $t_n - t_0$ is the number of years.

Example

Year-End	2004-12-31	2007-12-31
Year-End Revenue	9,000	13,000

Therefore, to calculate the CAGR of the revenues over the three-year period spanning the "end" of 2004 to the "end" of 2007 is:

$$\text{CAGR}(0, 3) = \left(\frac{13000}{9000} \right)^{\frac{1}{3}} - 1 = 0.13 = 13\%$$



Gives you an averaged “smoothened” rate for exponential growth and equals the exponential growth rate for a period of one year

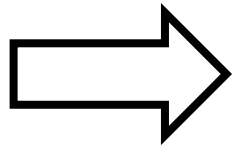
Definition of AAGR

The Annual Average Growth Rate is defined as follows:

$$\text{AAGR} = [(\text{Growth Rate})_y + (\text{Growth Rate})_{y+1} + \dots (\text{Growth Rate})_{y+n}] / N$$

y = specific year (starting point of the period of interest)

N = total period in years



Not applicable to exponential growth (use CAGR instead)

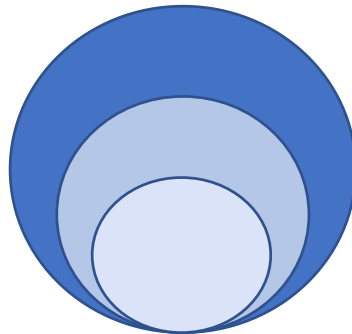
Worldwide market size and growth in the field of *in vitro* cancer diagnostics

Hits when using ["in vitro cancer diagnostics" market] as a search term in Google:

Cancer IVD Market size was valued at \$17,728 million in 2020 and is anticipated to reach \$22,430 million by the end of 2026 growing at a CAGR of 6.0% during the forecast period 2021-2026. (industryarc.com)

Oncology segment held around USD 19.2 billion in 2021... (gminsights.com)

The global cancer diagnostics market in terms of revenue was estimated to be worth 17.2 billion in 2021 and is poised to reach \$26.6 billion by 2026, growing at a CAGR of 11.5% from 2021 to 2026 (marketsandmarkets.com)



TAM ~ 18 billion USD, 6-11.5% CAGR (total IVD market in oncology)

Size of initial market niche

Define initial market niche: What are the annual sales of IVD indicated for colorectal cancer in Switzerland?

The screenshot shows the GlobalData website with the 'Who We Serve' section expanded. The navigation bar includes 'Who We Are', 'Industries We Cover', 'Who We Serve', and 'What We Offer'. The 'Who We Serve' section is divided into four columns: Corporates, Financial Institutions, Professional Services, and Other. A red diagonal text overlay reads 'Intro by Vida today!'.

Who We Serve	Corporates	Financial Institutions	Professional Services
	C-Suite	Investment Banking	Management Consulting
	Innovation and R&D	Equity Research	Legal & Accounting
	Market and Competitive Intelligence	Investment Management	Other
	Strategic Planning & M&A	Private Equity & Venture Capital	Academia
	Marketing		Government
	Business Development		Media & Advertising

- ➡ Even with very good data bases you potentially won't find all specific data
- ➡ In this case try to get rough estimates by (simplified) indirect calculations!

Calculating an estimate for *in vitro* cancer diagnostics in CH

Total drug sales in Switzerland were about 6 billion US\$ in 2019, of which 16% were anti-cancer drugs, equaling 960 million CHF (2019 Report of the Swiss Pharma Industry). The worldwide sales of anti cancer drugs in 2019 were 145 billion US\$ (Statista), meaning that the market share of Switzerland was about 0.66%.

In a very simplified way, one could hence assume that Switzerland might also have an approximate 0.66% market share for *in vitro* cancer diagnostics, whose annual sales were about 18 billion in 2020 (see previous slides). This would correspond to an **estimated volume of about 119 million US\$.**

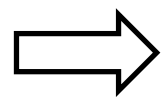
Important note: The total cancer diagnostics market includes tests that are carried out to determine if people have cancer and therefore also includes healthy individuals on whom the TheraMe! business model cannot be applied!

Calculating an estimate for *in vitro* colorectal cancer diagnostics in CH

Assuming a total annual volume of 119 million US\$ for cancer diagnostics in Switzerland (simplified estimate!) and an even distribution over the different cancer types (strongly simplified estimate), one could calculate the specific market for colorectal cancer as follows:

Target market size = 119 million US\$ x relative colorectal cancer incidence:

Number of cancer incidence ^{a, b}	Worldwide 2018	USA 2018	Germany 2018	Switzerland 2018	Luxemburg 2018	
All cancer types	18 078 957	2 129 118	608 742	56 506	3 271	
Colorectal cancer	1 849 518	155 098	58 047	4 681 (8.2%)	323	



Estimated size of the initially targeted marked niche = 119 million US\$ x 8.2% = 9.7 million US\$

But what percentage of this market could be realistically captured?

What is the market share of the strongest competitor?

Identify a competitor for benchmarking: Select a successful company with a product to which yours is potentially superior (or at least competitive) and provide all corresponding market and company data!

Comparison with existing diagnostic products

System	FDA-approved Companion Diagnostics Tests	FDA-approved Circulating Tumor Cell Count	THERAme 
Detection of individual resistances	✓	✓	✓
Comparison of 100+ therapy options	✗	✗	✓
Diagnosis before treatment	✓	✗	✓
Diagnosis without prior knowledge/ biomarkers	✗	✓	✓
Direct evidence for efficiency of therapy	✗	✓	✓
Costs per test & patient	~ 1,500-5,800 US\$ 	~350 US\$ 	~2500 US\$* 

*envisaged market price, internal consumable costs = 150 US\$ per screen

Comparison with existing diagnostic products

Diagnostic Name	Diagnostic Manufacturer	Cancer Type Therapy Trade Name (Generic)	Test / Kit Price \$	CAGR (2015-2025)
FoundationOne CDx	Foundation Medicine	Colorectal cancer Erbix (cetuximab) - BLA	5,800	
Praxis Extended RAS Panel	Illumina	Colorectal cancer Vectibix (panitumumab) - NDA		
Cobas KRAS Mutation Test	Roche Molecular Systems	Colorectal cancer Erbix (cetuximab) - BLA Vectibix (panitumumab) - BLA	160	4.1 %
Therascreen KRAS RGQ PCR Kit	Qiagen Manchester	Colorectal cancer Erbix (cetuximab) - BLA Vectibix (panitumumab) - BLA	200	
Dako EGFR pharmDx Kit	Dako North America	Colorectal cancer Erbix (cetuximab) - BLA Vectibix (panitumumab) - BLA	40	3.4 %

Let's have a closer look at the history of Foundation Medicine:

The history of Foundation Medicine

- 2010: Founded with a Series A investment of 25 million US\$
- 2012: First commercial assay marketed in 2012
- 2013: IPO (NASDAQ:FMI), raising 106 million US\$
- 2015: Roche acquires 56.3% shares for 780 million US\$
- 2018: Roche acquires remaining shares for 2.4 billion US\$
- 2018: 668 employees, 201,4 million US\$ revenue, ~95k kits sold, most important product: FoundationOne CDx at a price of ~5,800 US\$ per kit

100

U.S. Metastatic Cancer Patients
LEK market research

24
Get Single-Marker Testing

16
Get NGS Testing

60
Get No Molecular Testing

6
Get FMI Testing



FMI is growing faster than market (>50% YoY)



2010

Company Founded

2012

FoundationOne® launched

2013

FoundationOne®Heme launched

2016

FoundationACT® launched, FoundationFocus™ CDxBRCA - first FDA-approved companion diagnostic

2017

FDA approves FoundationOne CDx - the first broad companion diagnostic for solid tumors

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2020
Sales (test)			2K	9K	25K	33K	43K		95 K	
Revenue		2.06 M\$	10.6 M\$	29.0 M\$	61.1 M\$	93.2 M\$	116.9 M\$	152.9 M\$	200 M\$	430 M\$
Growth						52.5%	25.4%	30.8%		
Investment Series	25 M\$ A	17 M\$	59 M\$ B	165 M\$						

A Continuing Story of Growth and Execution



Most important facts to extract

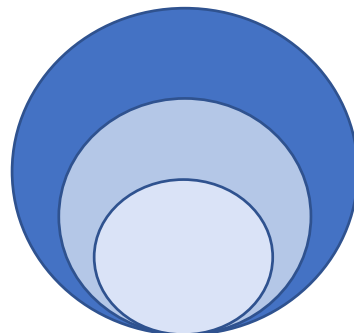
- Series A investment = 25 mio US\$ in 2010
- Takeover by Roche (56% just 5 years after company launch, rest in 2018) for a total of 3.18 billion US\$
- Sells kits at a unit price of 5.800 US\$
- Sales of 2k kits 2 years after company launch, 95k 8 years after company launch
- **6%** of metastatic cancer patients in the US get tested with a FM product

Most important facts to extract

- Series A investment = 25 mio US\$ in 2010
- Takeover by Roche (56% just 5 years after company launch, rest in 2018) for a total of 3.18 billion US\$
- Sells kits at a unit price of 5.800 US\$
- Sales of 2k kits 2 years after company launch, 95k 8 years after company launch
- **6%** of metastatic cancer patients in the US get tested with a FM product

Let's use this data to extrapolate the initial market potential of TheraMe!

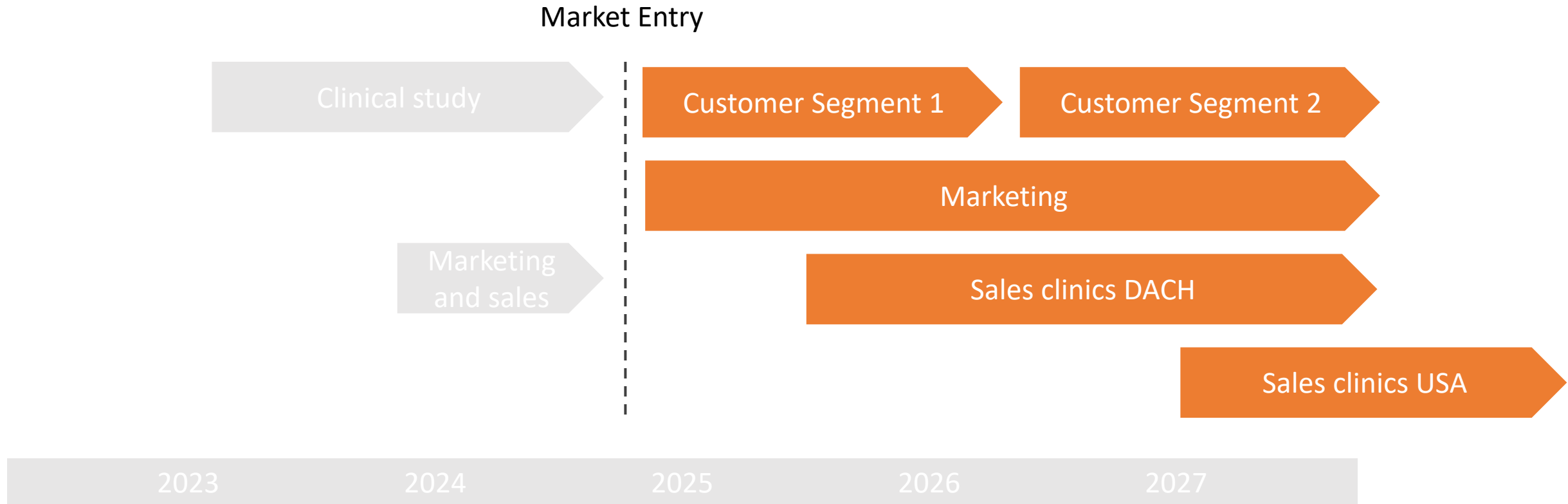
Country	# new colorectal cancer diagnoses/year	# of potential tests (6% patient reach)	Potential annual sales
CH	4681	281	1.6mio US\$
D	58 047	3483	20 mio US\$
US	155 098	9306	54 mio US\$



TAM ~ 18 billion USD, 6-11.5% CAGR (total IVD market in oncology)

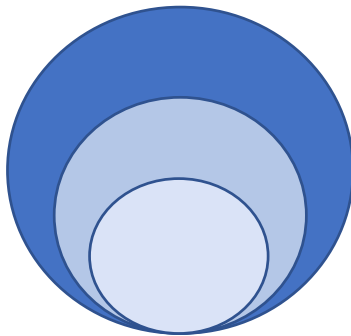
SOM ~ 1.6 million USD (6% of all colorectal cancer patients in CH)

Market entry strategies



Growth and scalability

- Expanding on additional markets (requiring additional approvals, but easy in e.g. additional EU countries once marketed in a single EU country)
- Expanding to different tumor types (warning: this requires additional clinical trials!)
- Expanding to different business models (e.g. making use of the acquired data for biomarker discovery)
- Launching advanced generations of the technology (note that this probably does not result in more tests per patient, but potentially in a higher market share)



TAM ~ 18 billion USD, 6-11.5% CAGR (total IVD market in oncology)

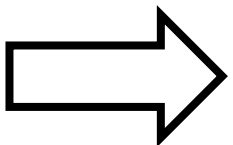
SAM ~ 76 million USD (6% of all colorectal cancer patients in CH, D & US)

SOM ~ 1.6 million USD (6% of all colorectal cancer patients in CH)

Market size and potential sales

Analyzing YOUR potential market is always based on estimates and assumptions. Depending on the data source, you will even get very different numbers from professional market analysts. To get a realistic idea, it is therefore very useful to perform complementary analyses and calculations:

- **Identify the total size of your target market using different databases and internet searches** (are the numbers I need already publicly available?)
 - **Calculate the market size indirectly** (e.g. multiply the relative incidence of your targeted cancer type with the total sales to get an estimate on indication-specific sales)
 - Look at the **sales of your main competitor(s)**
 - **Ask potential customers** (especially for B2B models they will have good data!)
- Total size of targeted market, still has to be multiplied with expected market share/penetration
- Probably mirrors your market potential better



In the very best case you should end up with coherent numbers for the different approaches. If not, rather go with the worst case estimate!

How to calculate potential market sizes in the health sector for entirely new approaches?

QALY = Quality-Adjusted Life Years:

- If e.g. a drug extends survival by one year, then its QALY value is 1.
- If a drug or clinical intervention makes blind people see for five years, then the QALY value is often estimated to be 5 times 0.3 (difference between blind and seeing) = 1.5

How much are the health care systems willing to pay for 1 QALY?

Determining the efficiency path to universal health coverage: cost-effectiveness thresholds for 174 countries based on growth in life expectancy and health expenditures

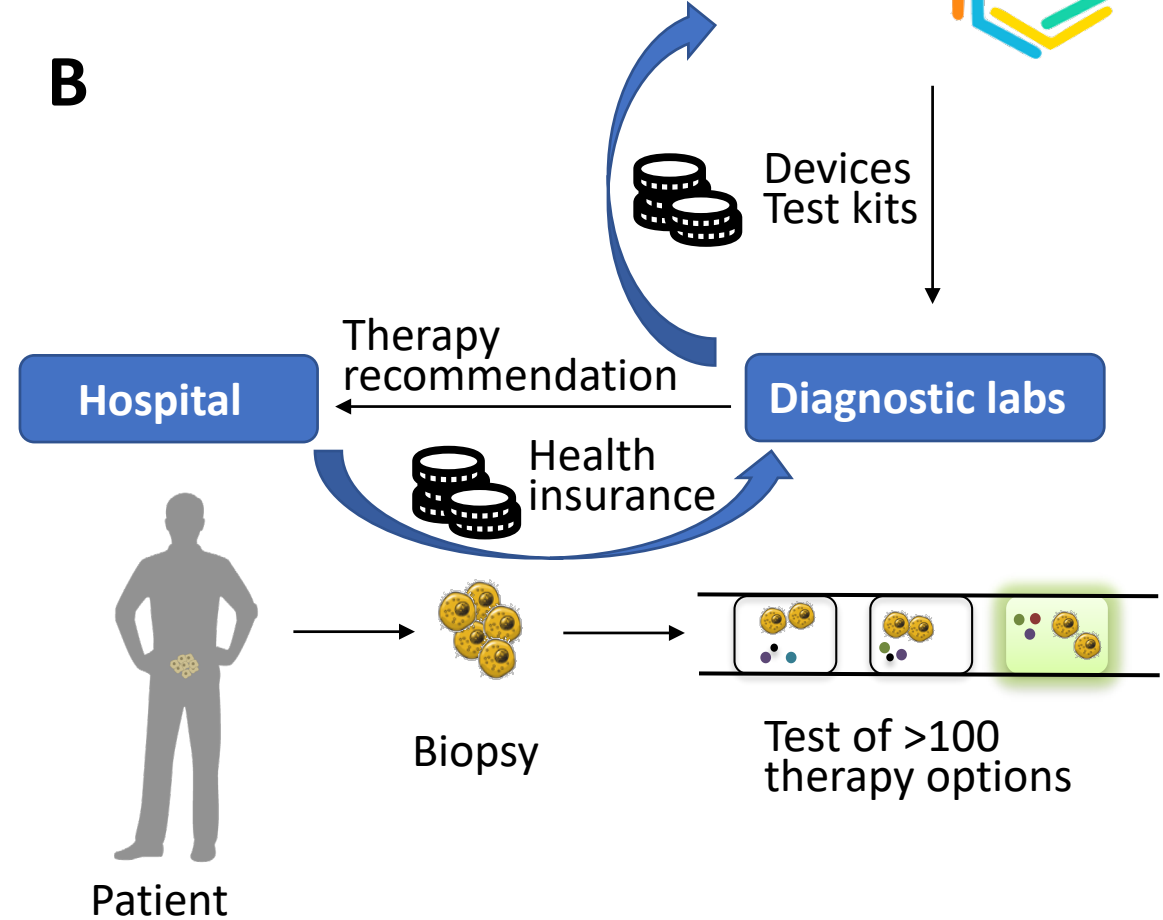
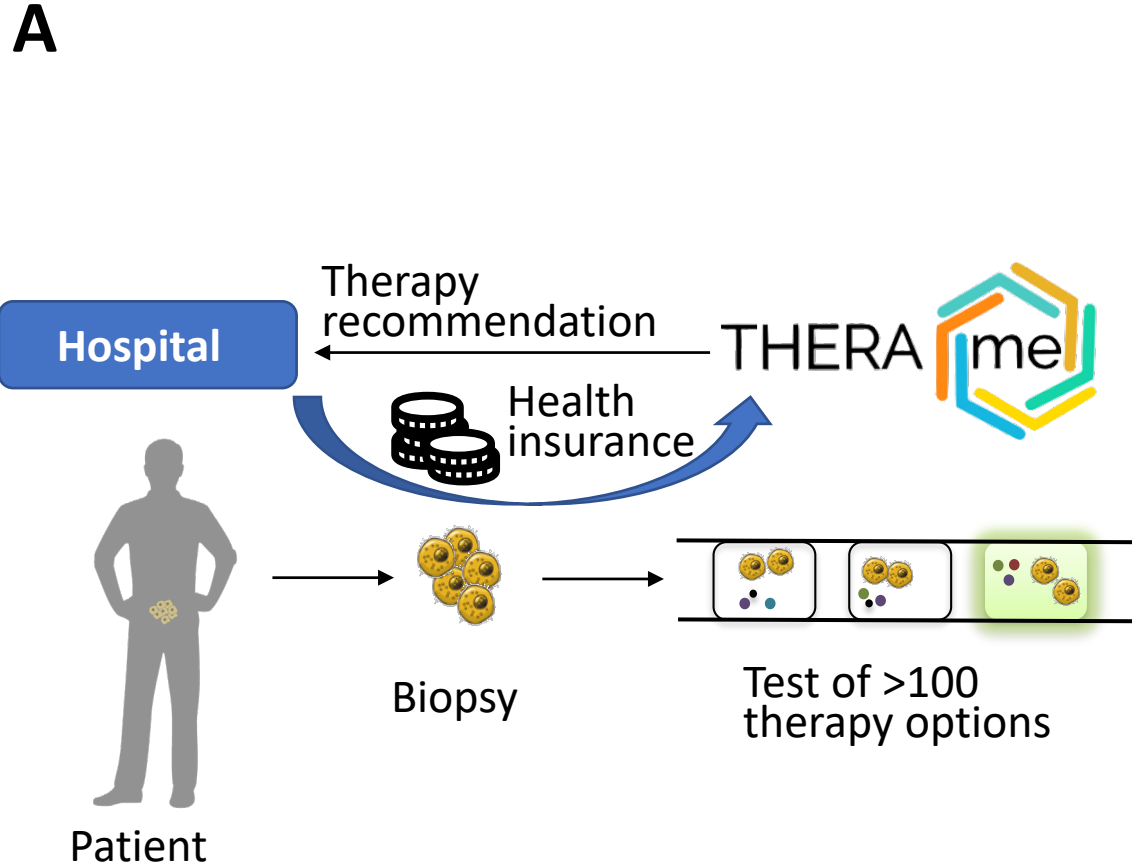
Andres Pichon-Riviere, Michael Drummond, Alfredo Palacios, Sebastián Garcia-Marti, Federico Augustovski



1 QALY in US = \$95 958

- **Note that this is much more than e.g. the price for a CDx test, which only provides support for a better treatment, but no direct life extension!**
- **Gives you an estimate on how much the treatment of deadly diseases may cost (averaged – there are outliers!)**

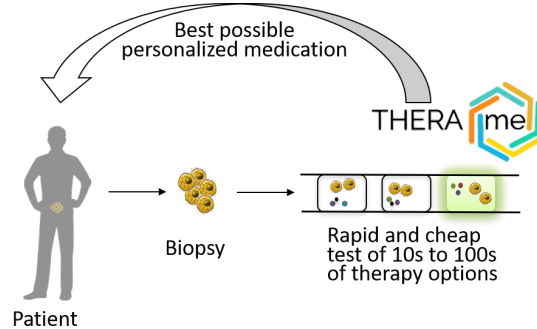
How to address patients as consumers?



➡ Which model do you prefer and why?

BIO-490 students tasks for today/ this week

- Get an introduction into GlobalData and perform searches
- Form groups and select an example innovation (hypothetical or real) for the group pitch. Select individual case study.
- Develop your example innovation into a first basic value proposition



- Compare it to what is already on the market

System	FDA-approved Companion Diagnostics Tests	FDA-approved Circulating Tumor Cell Count	THERAme
Detection of individual resistances	✓	✓	✓
Comparison of 100+ therapy options	✗	✗	✓
Diagnosis before treatment	✓	✗	✓
Diagnosis without prior knowledge/ biomarkers	✗	✓	✓
Direct evidence for efficiency of therapy	✗	✓	✓
Costs per test & patient	~ 1,500-3,500 US\$ 	~350 US\$ 	~2500 US\$* 

- Find market data on your innovation and prepare 1-2 nice slides summarizing the most important info: TAM, SAM & SOM
Good company for benchmarking (“this is the success story of a competitor, but our product is even better”)

Questions?

