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## Financing *Digital Health* start-ups in light of investor hype, business scaling and reimbursement challenges

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*Digital Health:  
Start-up Financing | Life Science Vertical RWTH Aachen*

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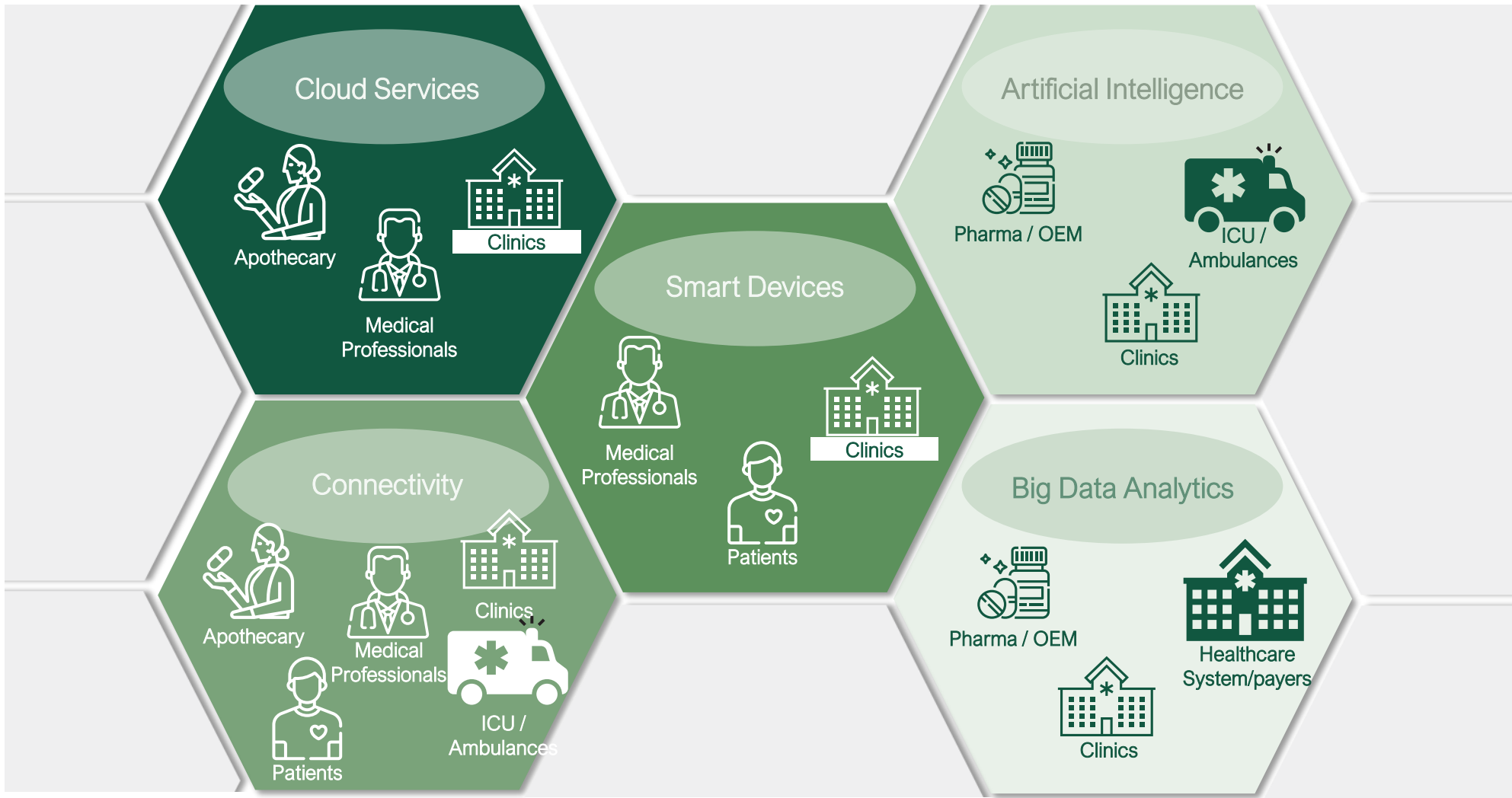
## Agenda

<b>1</b>	<b>Digital Health - a Megatrend of our time</b>	<b>3</b>
<b>2</b>	<b>Digital Health - Current funding environment</b>	<b>7</b>
<b>3</b>	<b>Key economic drivers &amp; challenges for a Digital Health business model</b>	<b>11</b>
<b>4</b>	<b>Case Studies</b>	<b>15</b>

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All stakeholders in the wider healthcare industry are users and contributors to increased and accelerated digitalization.



**Digitalization touches and adds value to every inch of the healthcare industry from the initial touchpoints with patients over enhanced diagnostic and medical interventions to the challenges of the supply chain logistics**

**1) Patient Journey (Telemedicine)**

- OTCs directly ordered through online pharmacies
- Rx prescribed by Tele-doctor to pharmacy (ePrescription)
- Patient Education with AR/VR

**2) Medical Research, Development & Science/Health Policy**

- Big Data Analytics – in silico even on a molecular level in drug R&D
- Combining long-term health data with socio-economic parameters

**3) Diagnostics**

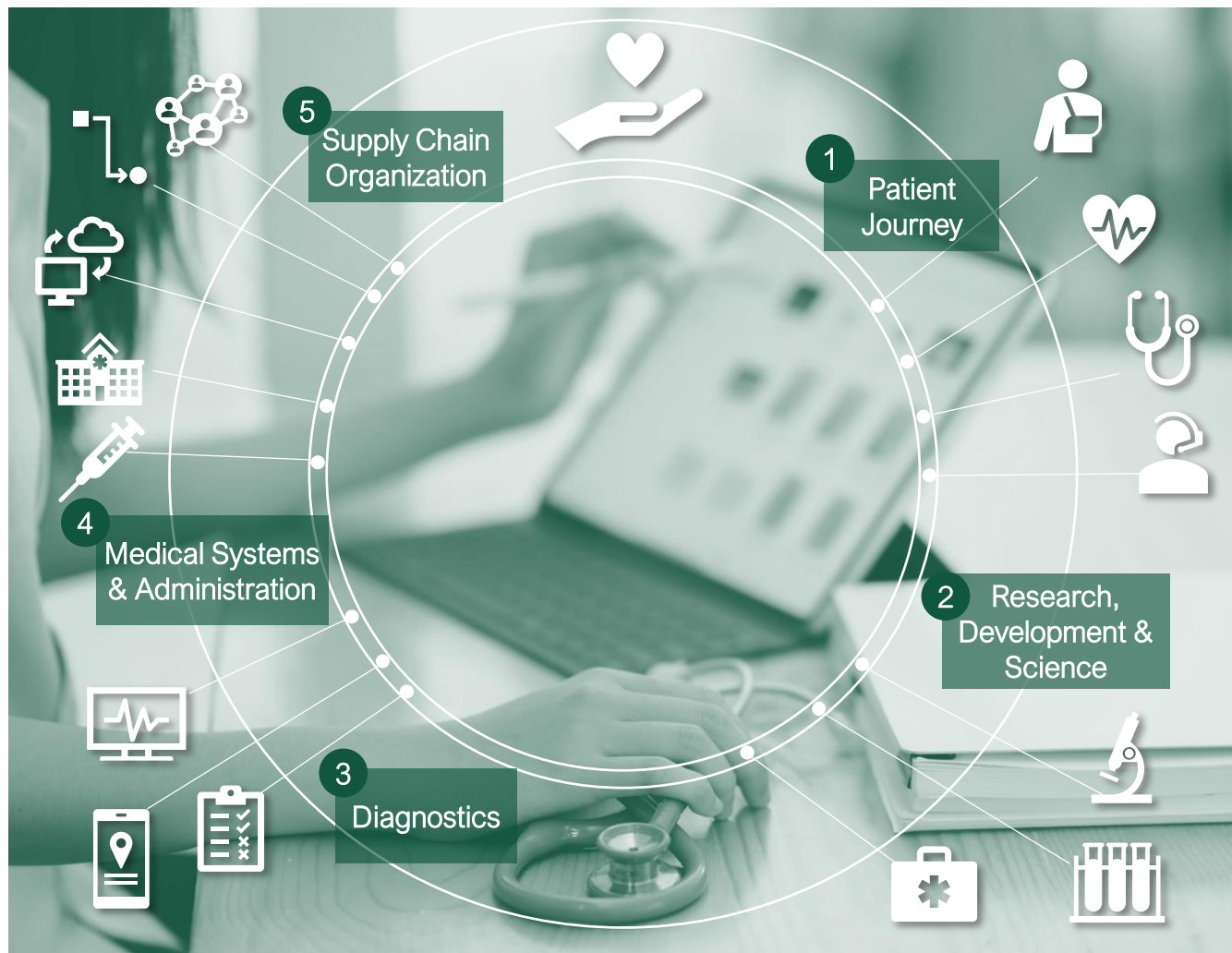
- Smart Devices
- Remote Patient Monitoring
- Digital Imaging with AI integration

**4) Medical Infrastructure & Administration**

- Organizational & resource efficiency
- Bots and AI Support
- Efficient billing and reimbursement

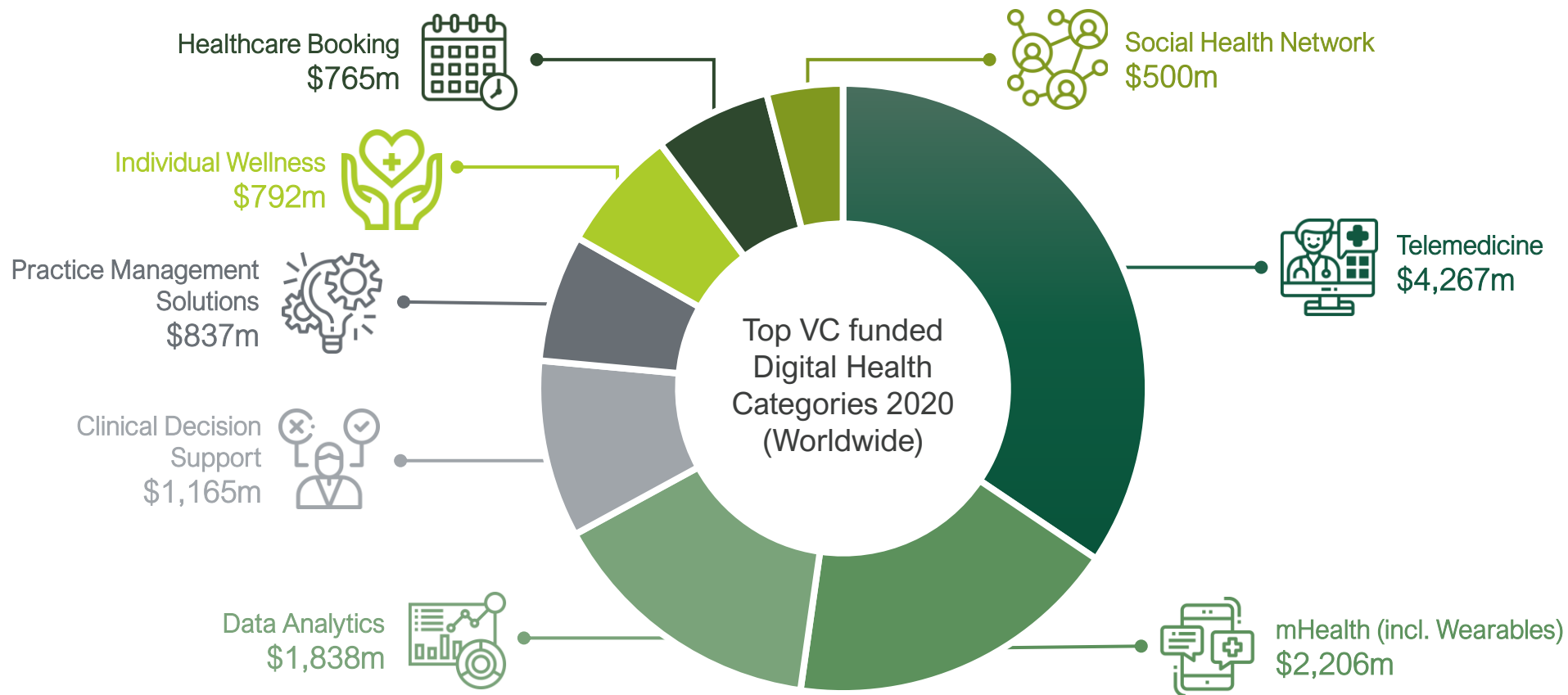
**5) Supply Chain / Sourcing**

- Precious goods / Cool chains
- Data security
- Real-time allocation



The largest 150 digital health start-ups have raised over \$20B in total/aggregate funding across 600+ deals from 900+ unique investors.

Digital health is the convergence of digital technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery to make medicine more personalized and precise.



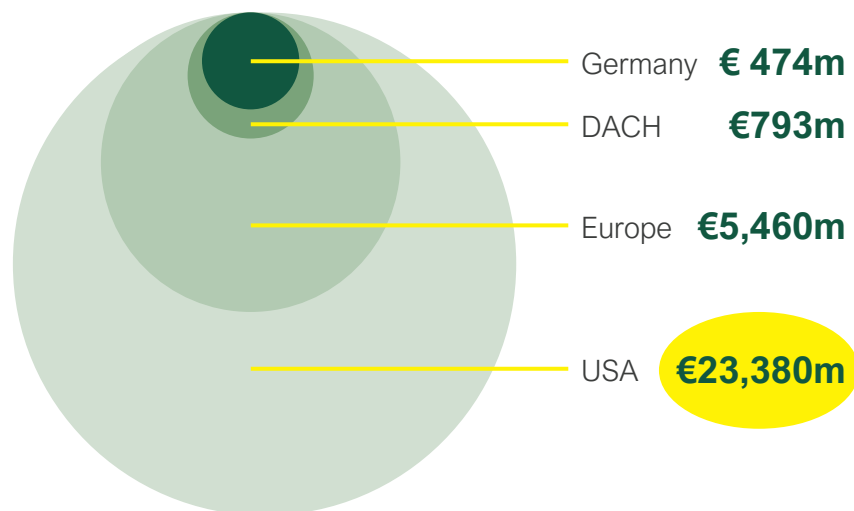
Source: Mercom Capital, 5-HAT, CB Insights, PP-Analysis

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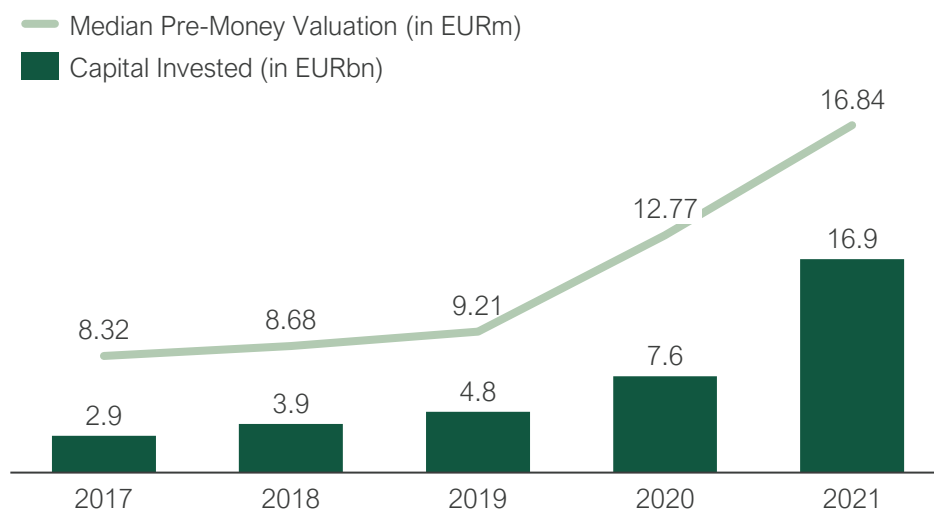
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**VC funding of Digital Health companies grew significantly – but funding & valuation hikes dominated by the huge US market!**

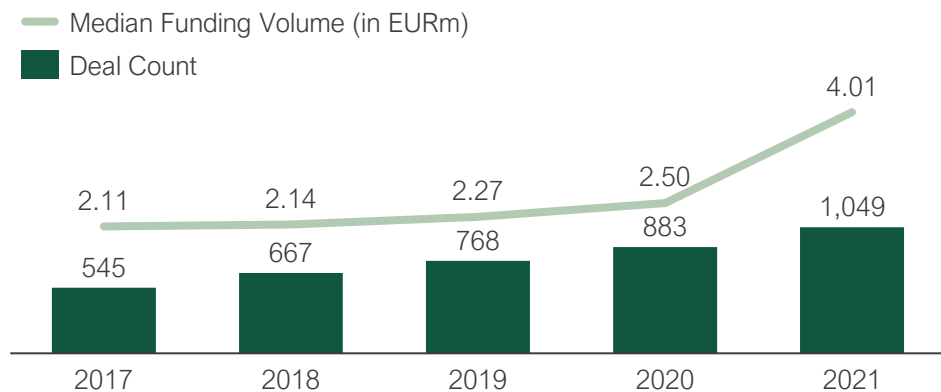
**Global digital health startups funding volume (last 5 years)**



**Global total capital invested and median pre-money valuation**



**Global median funding volume and deal count (last 5 years)**



**Top HealthTech funding rounds 2021**



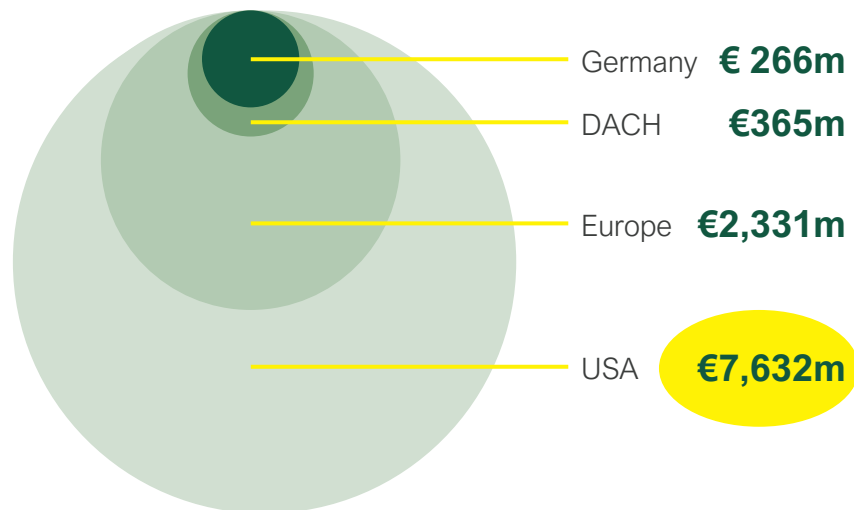
Source: Pitchbook Data Inc. PP-Analysis



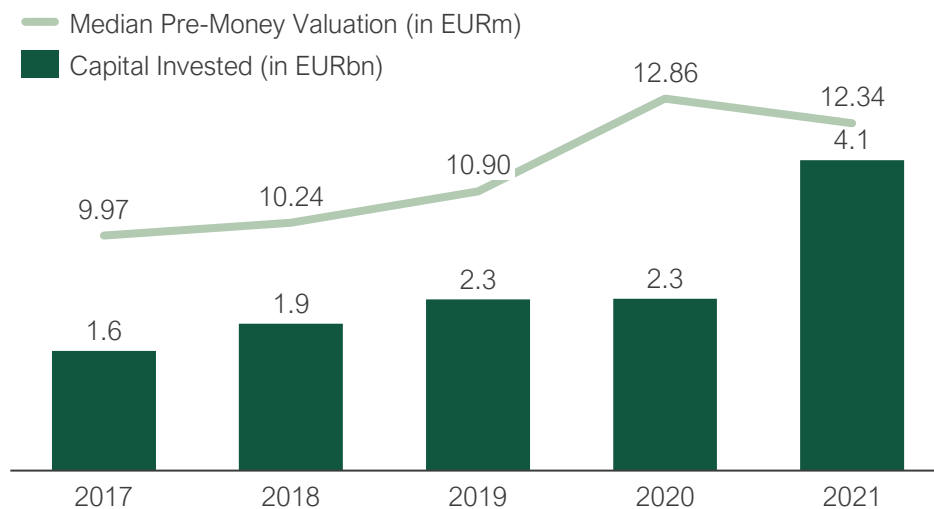
Seed & Early Stage (Series A)

**VC funding of Digital Health companies in Seed & Early Stage (Series A).**

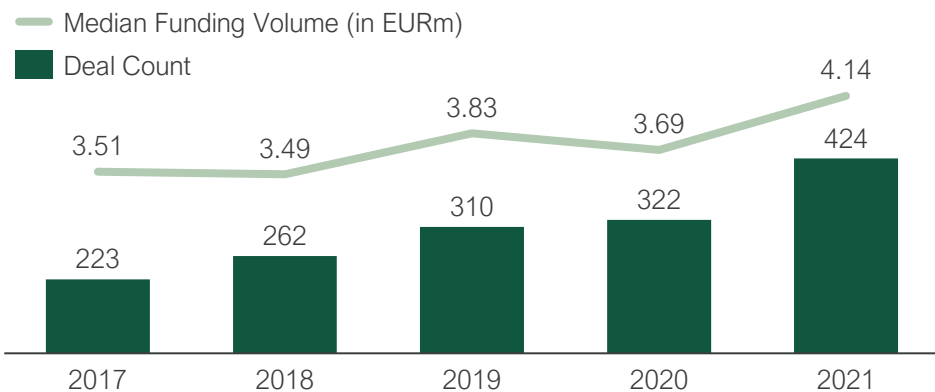
**Aggregate Global funding volume (last 5 years)**



**Global total capital invested and median pre-money valuation**



**Global median funding volume and deal count (last 5 years)**



Source: Pitchbook Data Inc. PP-Analysis

**The Top VC funding deals (2021) for digital health companies in Europe reveal the investor's appetite for later stage, scalable business models with a skew towards PoC / patient (consumer)-oriented models ... funding volumes are way below the US, though.**

Companies	Deal Type	Indication / Business Focus	Business Model	Company Country	Deal Size (EURm)	Deal Date	Pre-money
Oviva	Later Stage VC	<b>Diabetes</b>	Nutrition therapy/advice for T2D patients	Switzerland	<b>68.00</b>	01.09.21	111
Koa Health	Later Stage VC	<b>CNS / Mental Health</b>	Cognitive-behavioral therapy	Netherlands	<b>35.00</b>	09.02.21	n/a
EGYM	Later Stage VC	<b>Fitness</b>	Unique Fitness ecosystem	Germany	<b>34.85</b>	16.09.21	170
AdjuCor	Later Stage VC	<b>Cardio-Vascular</b>	Combination of implant and digital technology	Germany	<b>29.00</b>	09.06.21	123
Avi Medical	Early Stage VC	<b>GP / Telemedicine</b>	Telehealth primary care (GP) services	Germany	<b>28.50</b>	07.06.21	31
Quin	Later Stage VC	<b>GP / Telemedicine</b>	Symphom checker and GP telehealth services	Netherlands	<b>25.00</b>	18.01.21	75
ScreenPoint Medical	Later Stage VC	<b>Oncology (mamma)</b>	AI-driven imaging diagnostics for breast cancer patients	Netherlands	<b>23.67</b>	27.07.21	n/a
Kenbi	Early Stage VC	<b>Home Care</b>	Digitally powered home care services	Germany	<b>23.50</b>	16.12.21	n/a
Novadip	Later Stage VC	<b>Tissues regeneration</b>	Autologous cell therapies	Belgium	<b>20.27</b>	30.09.21	72
...							
Clue	Later Stage VC	<b>Women's Health</b>	Period and ovulation tracker	Germany	<b>16.95</b>	31.08.21	51
felmo	Early Stage VC	<b>Animal Health</b>	Mobile veterinary services	Germany	<b>15.00</b>	04.08.21	n/a
Dopavision	Early Stage VC	<b>Ophtalmology</b>	Digital treatment of childhood myopia	Germany	<b>12.00</b>	14.07.21	10
Humanoo	Early Stage VC	<b>Mental Health</b>	Online coaching for mental health/employee well-being	Germany	<b>10.00</b>	01.04.21	36
Actio	<b>Seed Round</b>	<b>Fitness</b>	Wellness/fitness coaching app	Germany	<b>8.50</b>	16.02.21	n/a
Clinomic	Early Stage VC	<b>Intensive Care</b>	AI-powered support of ICUs	Germany	<b>7.00</b>	19.03.21	3
MedKitDoc	<b>Seed Round</b>	<b>GP / Telemedicine</b>	Combining med devices, smartphone and telehealth	Germany	<b>7.00</b>	28.12.21	n/a
HelloBetter	Early Stage VC	<b>Mental Health</b>	Online coaching / stress, burnout etc.	Germany	<b>6.00</b>	27.10.21	n/a
Lindera	Early Stage VC	<b>Fall Prevention / Fitness</b>	3D Motion Tracking for (elderly/disabled acre), fitness	Germany	<b>6.00</b>	25.11.21	n/a

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## Reimbursement – often viewed as the holy grail in a healthcare business model – key requirements for “DiGAs” in Germany.

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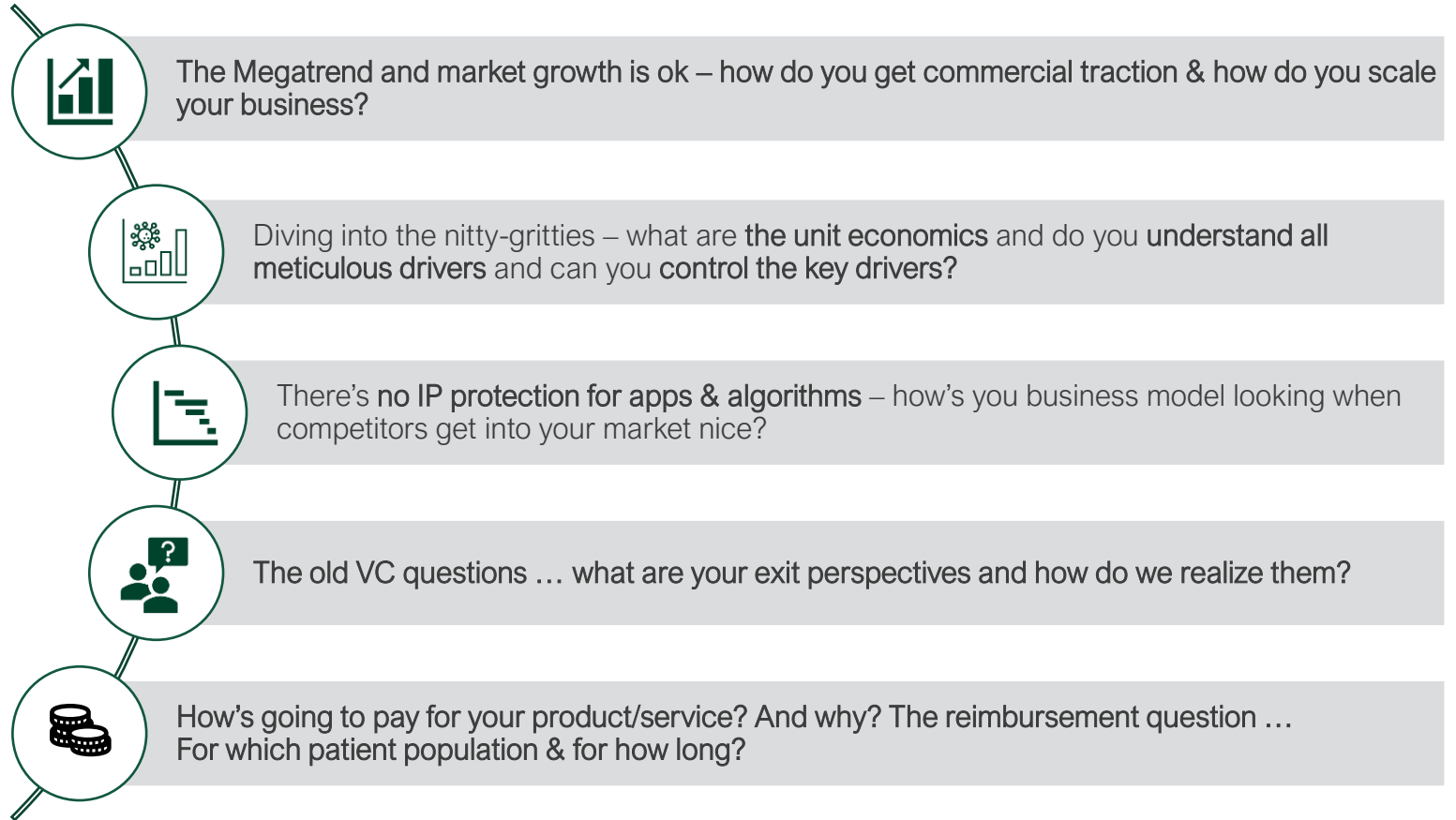
- Digital Health Apps (“DiGAs”) were formally introduced and legally established for reimbursement with the *Digitale-Versorgung-Gesetz (DVG)* on **19 December 2019**: since then, ca. 73m persons insured (GKV) can legally claim the prescription or use of a DiGA for their specific (chronic) indications.
  
- REQUIREMENTS
  - Comply with new **Medical Device Regulation (MDR)** [class I or IIa] >> approval process & procedures via BfArM
  - Comply with new *Digitale-Gesundheitsanwendungen-Verordnung (DiGAV)*
  - **Applicant must provide evidence for „positive effect on medical care“** (*positiver Versorgungseffekt*)
  - FRONTEND
    - The „App“ / solution for **patients** (and possibly: +healthcare providers)
    - **(Tele-)Services** by the App provider
    - **Diagnostics**: connection/link with sensors etc.
    - **Therapy**: dashboards, pat journals, patient education, medical advice, therapy goals/plans/monitoring/ ...
  - BACKEND
    - Secure data management incl. Adaptability and interoperative standards
    - Secure user administration and access logs/documentation
    - **Strict adherence to GDPR (DSGVO) requirements**
    - (Secure) data exchange with statutory healthcare system (GKV)
    - Management of billing/Reimbursement process with other integrated providers & GKV systems
    - Content Management
  - **Fulfilment of Checklist 1 & 2 according to DiGAV**  
**!! Possible Problem: data management & hosting outside the EU (>> Art. 45 DSGVO)**

## “DiGA” Reimbursement – Evidence of positive effect on medical care (*positiver Versorgungseffekt*)

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- Possible categories:
  - *Medizinischer Nutzen (mN)*
  - *patientenrelevante Struktur- und Verfahrensverbesserung (pSVV)*
  
- REQUIREMENTS
  - Define relevant patient population ... **subgroup analysis ok >> but reimbursement will then hold for those subgroups only!**
  - Definition of indication in accordance to ICD-10 (3/4 digit code)
  - Comparator study must be conducted in **accordance with the relevant applicable scientific standards and evaluated by independent body (CRO)**
  - Retroactive comparison is generally possible (§10 DiGAV)
  - **Study must be conducted in Germany!**
  - **Study must be quantitative**, only qualitative assessment is not permitted
  - Study must be registered in public study register
  - Study results must be published

**Challenges to the Digital Health model from a VC perspective.**



\* High-level estimate by Proventis based on YTD actuals

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## Company A: Early-stage funding and strategic partnering for *digital imaging software* company.

### Case A

#### Company A

##### Product:

Software

- Digital Imaging (X-ray, CT, diagnostics, interventions)

##### Advantage:

Unmet medical need

- Better picture quality
- Less x-ray radiation

##### In need of:

Funding + strategic partnership



1

#### Challenges

- Typical startup situation (small team, great concept, little money, ...)
- Science-heavy management team
- No traction in the huge x-ray market
- Lack of clinical data

2

#### Market Feedback

- Skepticism about market success
- Independent commercialization questioned
- Strategic Investors (OEMs): “not invented here”
- Will clinical data grant reimbursement?
- Hospital customer: “labor law issue!”

3

#### Solution

- Private funding failed
- BUT company was awarded  
→ Public sector (EU) funds for further development and data generation



**Company B: Series A funding *logistics tech company with focus on cool chain logistics for pharma and medtech products.***

**Case B**

**Company B**

**Product:**

End-to-end cool chain logistic solutions for pharma/medtech

- Hardware with sophisticated sensors
- Cloud-based real-time monitoring and tracking; automation of GDP documentation

**Advantage:**

Integrating hard- and software Solutions; building truly unique Pharma-focused supply chain ecosystem

**In need of:**

Funding



1

**Challenges**

- Typical startup situation (small team, great concept, little money, ...)
- Crowded space
- Hardware products still in development or validation phase

2

**Market Feedback**

- Skepticism about competitive edge/USPs
- Tapping on direct funding from statutory healthcare system not possible
- Many tech investors do not understand pharma needs, GDP, ...
- Some tech investors don't like hardware, tried to convince mgmt. to skip hardware

3

**Solution**

- Venture round could NOT be achieved
- EXIT Preparation with support of strategic investor

## Therapeutic Gaming: Series A funding and strategic partnering for *therapeutic gaming company in the elderly care/CNS field*.

### Case C

#### Product:

Unique therapeutic gaming solution with individualized calibration via tof camera and easy-to-handle console

#### Advantage:

Holistic product concept covering i) elderly care homes, ii) ambulant (elderly) care and iii) [later] specific areas in Parkinson disease

#### In need of:

Funding + strategic partnership



1

#### Challenges

- Typical startup situation (small team, great concept, little money, ...)
- Somewhat complex funding history
- Compelling real-world evidence in elderly care, but only limited data in CNS field only
- More complex business model, no app

2

#### Market Feedback

- Many VCs don't like complex cap tables
- Skepticism about scaling and reimbursement beyond project-based funding in elderly care homes
- Elderly care market not regarded as "sexy"
- Pharma/medtech investors require more clinical data for CNS perspective

3

#### Solution

- Focus on **operational growth and strategic partnering** in the elderly care/nursing home market
- **Leverage backing by statutory health insurance fund in Germany**
- Envisioning **VENTURE DEBT** business case & funding model

## VR solutions for Mental Health: Seed funding and strategic partnering for mental health/relaxation with sophisticated VR solution.

### Case D

#### Product:

Unique VR solutions (tech platform and content) for mental health/relaxation in various healthcare, well-being and consumer market verticals

#### Advantage:

Sophisticated, holistic concept for mental relaxation with truly immersive 3D experiences accompanied by binaural beats

#### In need of:

Funding + strategic partnership



1

#### Challenges

- Typical seed situation (very small team, great concept, very little money)
- Too many options/leads/verticals to be grasped and followed in a structured way

2

#### Market Feedback

- Too early for VCs
- Skepticism about scaling
- Uncertainty about business model and routes to be followed ...
  - Medtech product,
  - B2B product for employee-wellbeing;
  - B2B2C or X2C model in global consumer markets

3

#### Solution

- Re-focused funding plan for *lower hanging fruits* and immediate commercialization options
- 1<sup>st</sup> closing with new high-calibre business angels secured
- **BOOTSTRAPPING** model and 2<sup>nd</sup> closing with existing / selected new BAs

We would be happy to meet you personally and support you in an advisory capacity.



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