Multidimensional challenges & opportunities in healthcare sector

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Global top 10 leading cause of death

Diarrhoeal diseases: 1,450,000 deaths
Diabetes mellitus: 1,490,000 deaths
Dementia: 1,590,000 deaths
COVID-19: 1,800,000 deaths
Neonatal conditions: 1,960,000 deaths
Lower respiratory infections: 2,590,000 deaths
COPD: 3,220,000 deaths
Cancers: 10,000,000 deaths
Ishaemic heart disease: 8,880,000 deaths
Stroke: 6,190,000 deaths

Source: World Health Organization
Burden of treatment cost, US (billion $):

- Diarrhoeal diseases: <1 B $
- Diabetes mellitus: 237 B $
- Dementia: 305 B $
- COVID-19: 17 B $
- Neonatal conditions: 26 B $
- Lower respiratory infections: 40 B $
- COPD: 49 B $
- Stroke: 53 B $
- Ishaemic heart disease: 216 B $
- Cancers: 209 B $

Source: National Center for Disease Prevention and Health Promotion
Mental health (deaths global, cost in US):

- **Suicide**: 700,000 deaths
  - Mental treatment costs in US 2020: 238 B $

- **Drug overdose**: 500,000 deaths
  - Tangible cost of drug abuse: 600 B $

- **Homicide**: 500,000 deaths
  - Suicide: 700,000 deaths

Cost for violence victims: 214 B $

Tangible cost of drug abuse: 600 B $

Source: United Nations Office of Drugs and Crime & National Center for Disease Prevention and Health Promotion
It’s 1 diagnose, but 101 real-life outcomes:

- **Overweight**: 337,000,000 patients
- **Limb amputation**: 42,000,000
- **Vision loss**: 21,000,000
- **Diabetes mellitus**: 422,000,000 patients
- **Dementia**: 55,000,000 patients
- **Diabetes with dementia**: 3,600,000 patients

Human resources, number of population per single physician:

- Estonia: 289
- Europe: 232
- Americas: 353
- Western Pacific: 531
- Eastern Mediterranean: 914
- Southeast Asia: 1147
- Africa: 3623

Source: World Health Organization
Providing improvement means providing meaningful change means cost returned
### Drug and Sponsor Summary (2026 Forecast)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Sponsor</th>
<th>2026 forecast (B$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teprotumumab</td>
<td>Horizon Therapeutics</td>
<td>3.4</td>
</tr>
<tr>
<td>Ozanimod</td>
<td>Bristol Myers Squibb</td>
<td>2.5</td>
</tr>
<tr>
<td>Sacituzumab/ Govitecan</td>
<td>Immunogenics/Gilead</td>
<td>2.4</td>
</tr>
<tr>
<td>Risdiplam</td>
<td>Roche</td>
<td>2</td>
</tr>
<tr>
<td>Rimegepant</td>
<td>Biohaven Pharmaceuticals</td>
<td>1.6</td>
</tr>
<tr>
<td>Ripretinib</td>
<td>Deciphera Pharmaceuticals</td>
<td>1.6</td>
</tr>
<tr>
<td>Lurbinectedin</td>
<td>Jazz Pharmaceuticals</td>
<td>1.5</td>
</tr>
<tr>
<td>Belantamab mafodotin</td>
<td>GlaxoSmithKline</td>
<td>1.3</td>
</tr>
<tr>
<td>Tucatinib</td>
<td>Seagen</td>
<td>1.2</td>
</tr>
<tr>
<td>Avapritinib</td>
<td>Blueprint Medicines</td>
<td>1.0</td>
</tr>
<tr>
<td>Tazemetostat</td>
<td>Epizyme</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**TOTAL 19.5 B$**

### Clinical Trials and Approvals (FDA, 2020):

- **63 medical devices**
- **Number of clinical trials Running at 2020**: 12,288
- **52 novel drugs approved**
- **11 potential blockbusters**

**Source:** Nat Rev Drug Discov 20, 85-90 (2021) & World Health Organization
Drug development: cost or opportunity?

- Out-of-pocket cost per approval: 1395 million USD
- Capitalized cost per approval: 2558 million USD
- Post approval R&D: 2870 million USD
- Trials per approval: 19 million USD

Source: J Health Econ 47, 20-33 (2016) & Jama Medicine 178(11), 1451-1457
Class III device development\(^1\)

- Capitalized cost per approval: 526 million USD
- Out-of-pocket per approval: 54 million USD
- Trials per approval: 2.2 million USD
- Post approval R&D: 6 million USD

Class II device development

- Capitalized cost + trials, marketing & production: 25.5 million USD
- Out-of-pocket per approval: 2-5 million USD

Timeframe (months)\(^2\)

- PMA: 40
- Lab R&D: 24
- Clinical R&D: 80
- 510(k): 20


\(^2\) Source: Mark Drlik, Starfish medical devices commercialization tools. 2020.
<table>
<thead>
<tr>
<th>Device</th>
<th>Design complete?</th>
<th>Human Clinical Studies Required / Completed</th>
<th>Regulatory Clearance and Classification (FDA)</th>
<th>Commercial Sales</th>
<th>Time, pre-seed to development complete (years)</th>
<th>Amount Raised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation Device</td>
<td>YES</td>
<td>YES / YES</td>
<td>YES – Class III</td>
<td>YES</td>
<td>9,5</td>
<td>$ 77 M</td>
</tr>
<tr>
<td>Eye Implant</td>
<td>YES</td>
<td>YES / NO</td>
<td>NO – Class III</td>
<td>NO</td>
<td>6</td>
<td>$ 42 M</td>
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<tr>
<td>Optical Cart-Based System</td>
<td>YES</td>
<td>YES / YES</td>
<td>YES – Class II</td>
<td>PENDING</td>
<td>N/A</td>
<td>$ 5 M</td>
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<tr>
<td>Software as a Medical Device</td>
<td>YES</td>
<td>NO</td>
<td>YES – Class II</td>
<td>YES</td>
<td>N/A</td>
<td>$ 3,2 M</td>
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<tr>
<td>Diagnostic Device</td>
<td>YES</td>
<td>NO</td>
<td>YES – N/A</td>
<td>YES</td>
<td>5</td>
<td>$ 24,6 M</td>
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<tr>
<td>Blood Treatment Device</td>
<td>YES</td>
<td>YES / YES</td>
<td>YES – Class II</td>
<td>PENDING</td>
<td>N/A</td>
<td>$ 500 M</td>
</tr>
<tr>
<td>PoC Blood Assessment</td>
<td>YES</td>
<td>NO</td>
<td>YES – Class II</td>
<td>YES</td>
<td>6,5</td>
<td>$ 17,3 M</td>
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<tr>
<td>Light Therapy</td>
<td>YES</td>
<td>NO</td>
<td>YES – Class II</td>
<td>YES</td>
<td>N/A</td>
<td>$ 14 M</td>
</tr>
<tr>
<td>Novel Ultrasound Device</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>5</td>
<td>$ 20,5 M</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 years</td>
<td>$ 25,5 M</td>
</tr>
</tbody>
</table>

*Source: Mark Drlik, Starfish medical devices commercialization tools. 2020.*
Why do I need the accelerators here?
It is like leaving a parallel parking space

Side mirror – a cheap and briefly used assistant for safely exiting to busy street

Accelerator – a cheap and briefly used assistant for safely exiting to busy street of healthcare developments