Precision medicine challenges and opportunities

While medical treatments often deliver significant improvements, many patients struggle with **trade-offs** that come from using a product designed to be **one-size-fits-all**. To address these **deficiencies**, the medical technology and life science industries, broadly defined, should continue to turn to precision medicine – treatments **designed to work for individuals**.

Drivers of and barriers to precision medicine

Drivers

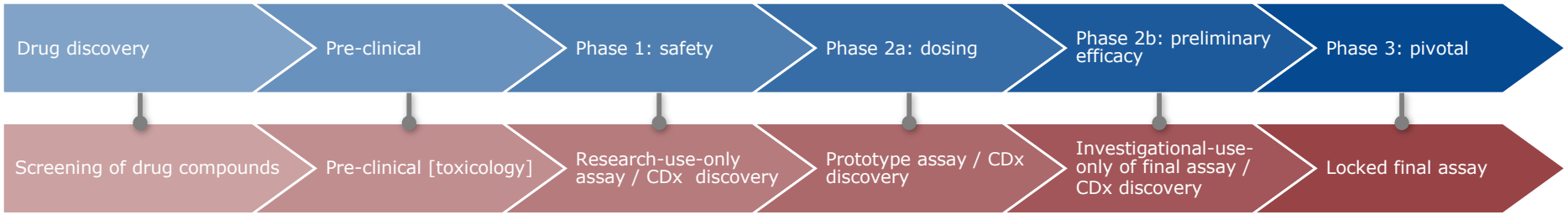
- Efficacy and safety
- Reduced unneeded treatment
- Lower treatment costs and perceived lower total costs
- Patient compliance and satisfaction
- Political tension and cost pressure on government funded healthcare
- Cell and gene therapy

Barriers

- Number and size of clinical studies
- Manufacturing costs
- Marketing and other expenses to serve smaller markets
- Diagnostic expenses
- Alternative ways to reduce need (e.g., dosing, finding an alternative target or mechanism)

Relationship between biomarker and drug development pathways

Drug R&D pathway



Biomarker/companion/complementary diagnostics pathway leading to commercialization

Strategic directives for various medical technology fields

Therapeutics	▪ Utilize genome- or other **omics**-based therapeutic development, which can help screen for compounds that yet have broader use for targets with low genetic variation ▪ Identify **companion** *or* **complementary** ***diagnostics***, as early in the process as possible, in order to better select patients during clinical studies, and get timely co-approval during the regulatory process ▪ Apply active post-hoc **genomic assessment**, especially for somatic (acquired) mutations in oncology ▪ Create the infrastructure to go to ***nichebusters*** from blockbusters
Diagnostics	▪ Use **state-of-the-art tools** to target novel biomarker discovery and validation ▪ Invest in blood testing technologies replacing invasive biopsies, so-called **liquid biopsies** ▪ Work with pharma and biotech firms early to identify, validate, and gain approval for **companion** or **complementary diagnostics** ▪ Start assessments with **medical device** companies to identify where the personalized approach can be applied, something yet in its infancy
Medical devices	▪ **Get in the game**. Medical devices could also benefit from better patient selection during clinical studies and subsequent medical use
Information technology	▪ Apply **machine learning** to large genomic data sets ▪ Go beyond and integrate other **biomarker types**, such as immunoassays and metabolomics in the big data collection and analysis ▪ Take on risk assessment and personalization for **complex disorders** ▪ Pursue complex **health economic** analysis in partnership with the therapeutic, diagnostic, and other medical technology firms
Life science tools	▪ Identify the next research **capacity bottleneck**, rather than chasing current competitors ▪ Add **machine learning** capabilities