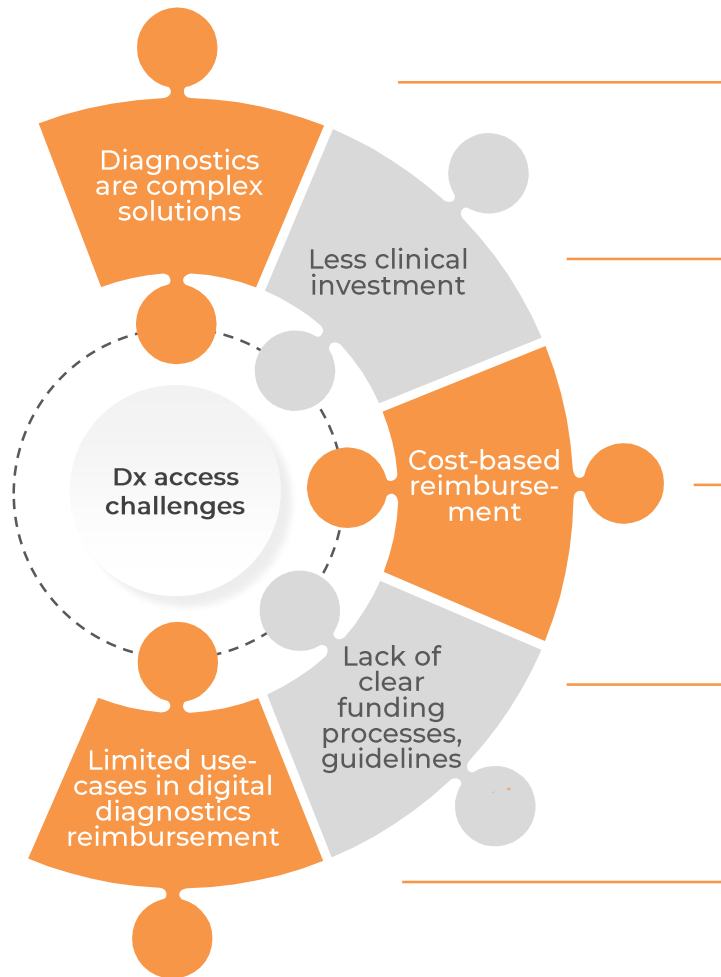


# 5 diagnostics (IVD) access challenges & implications



1

In vitro diagnostics are complex solutions. Instruments, tests, software and algorithms contribute to the value of the entire solution, to accurate and timely diagnostic information. Instruments and software improve operational efficiency, while tests and algorithms medical decisions, resource use and patient outcomes → *Capture holistic value of the entire solution by taking into account all relevant players (laboratory, hospital, physician, patients, society) in the healthcare delivery, over time*

2

The peak sales of diagnostics solutions is much lower than innovative medicines'. Manufacturers have less financial means to invest in large scale clinical trials, supporting access and adoption → *Utilize regulators' growing evidence requirements to increase development budget. Apply Real World Evidence (RWE) techniques*

3

Reimbursement systems in general do not incentivize the development of high medical value diagnostic solutions. Reimbursement & pricing are mainly based on testing methods, level of automation, time required to generate results → *On long-term: advocate for Health Technology Assessment (HTA) and value based reimbursement. On short-term: initiate outcome-based payer agreements*

4

Reimbursement pathways in general lack clear processes, guidelines, and most importantly systematic HTA's. Top-down, pharmaceutical-like reimbursement applies in a few countries, bottom-up, hospital-based funding is quite common → *Factor in longer reimbursement processes, be open to experiment, be ready for field-based market access solutions*

5

There are increasing number of digital diagnostics solutions, disrupting current IVD business model. These products enable the combination of physiological, behavioural and biological patient data to generate actionable insights. Classical reimbursement pathways do not, or partially cover these solutions, they tend to fall in-between current healthcare funding options → *Be open for alternative market access options, experiment, initiate pilot payer agreements*