Manufacturer evidence must clearly support positioning the test in standard of care patient management. The required evidence hurdle is not as high as for medicines, at least for now.

Regardless of pathway, decisions regarding reimbursement and adoption of new technology are diverse both across and within countries with varying levels of required evidence. Regardless of reimbursement decisions that may take place on a national or regional level, the final decision will likely be negotiated by facilities and will be focused on the price.

Access for a POC test will be complex:

Regardless of pathway, decisions regarding reimbursement and adoption of new technology are diverse both across and within countries with varying levels of required evidence.

Engage early with key stakeholders in order to understand the unique challenges and opportunities for your technology.