When Precision Meets Decision

Is It Time to Evolve Current Approaches to Health Technology Assessments for the Evaluation of Precision Oncology Therapeutics?

3 December 2021

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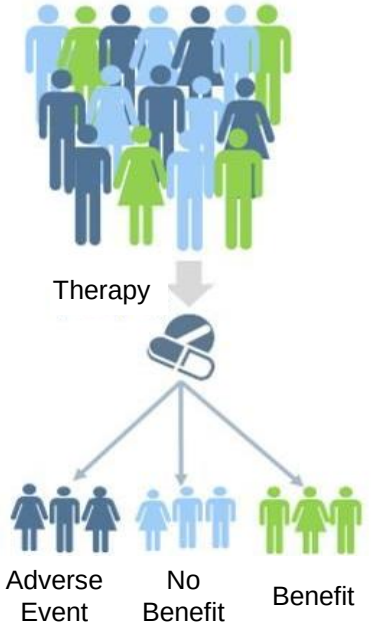
Introduction

Scientific advancements over the past two decades have ushered in a new paradigm of precision medicine, which is changing drug development and care delivery.

Precision oncology, in particular, is redefining how we view cancer, from an organ-specific to a molecular disease, with therapeutics targeting increasingly smaller and better-defined patient populations.

Precision Medicine

One Size Fits All Medicine → Stratified Medicine → Precision Medicine



Patients grouped by:

- Disease subtypes
- Risk profiles
- Molecular biomarkers
- Clinical features
- Demographics
- Socio-economics

Individual patient level

- Omics
- Lifestyle
- Preferences
- Health records
- Compliance
- Exogenous factors

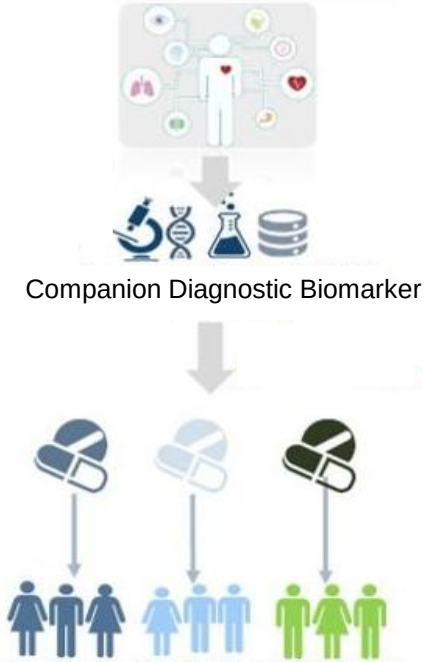
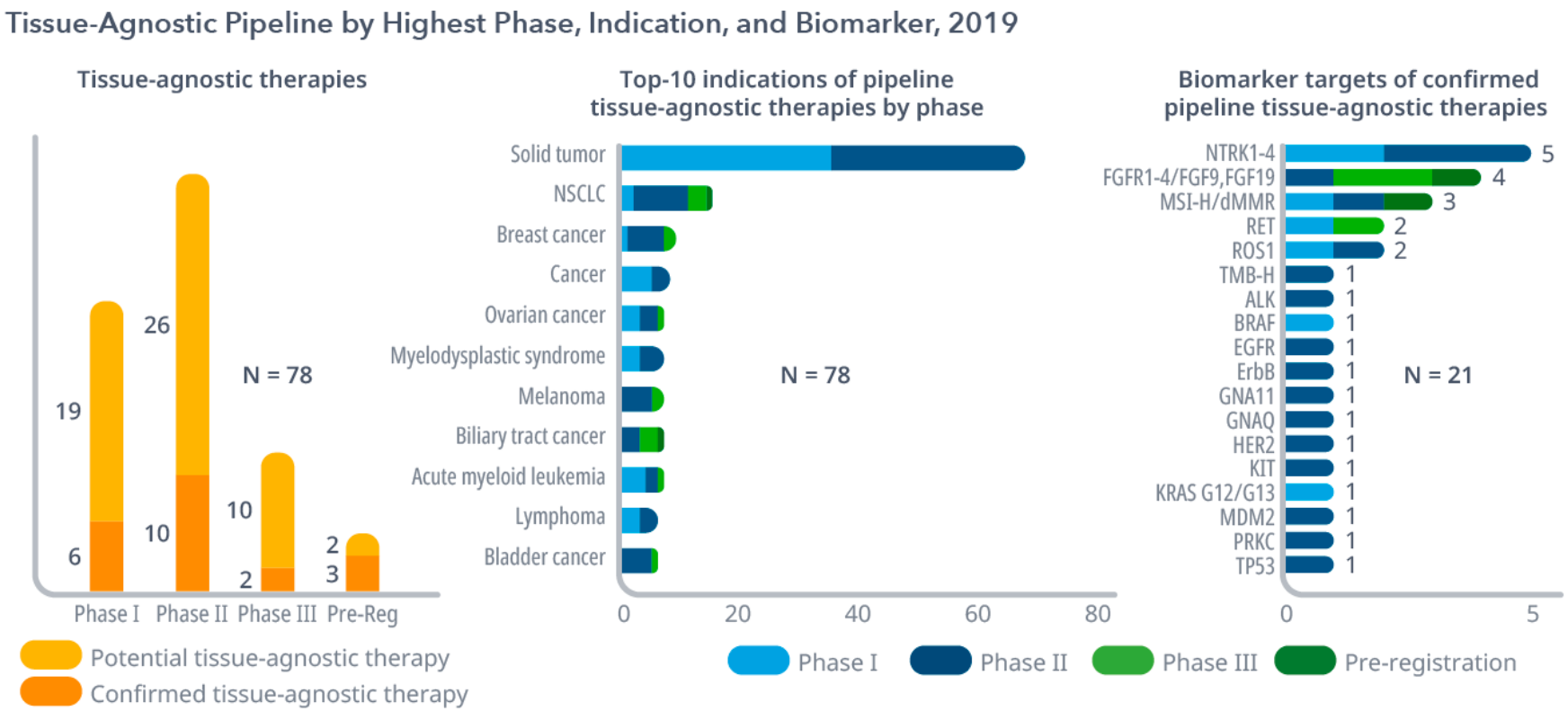


Image adapted from Global Precision Medicine Growth Opportunities Forecast To 2025, Growth & Opportunity (frost.com).

Precision Oncology and Tumour-Agnostic Therapies



~80 molecules with potential tumour-agnostic indication are being developed, of which **~20 have a confirmed biomarker target**.

Reference: https://www.iqvia.com/insights/the-iqvia-institute/reports/supporting-precision-oncology

Challenges of Assessing Precision Oncology Therapeutics

Genomic Sequencing

Affordability

Small Populations

Expert Working Group

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Critical Considerations for the Assessment of Precision Oncology Therapeutics

- Early and broad engagement with all partners through a process that appreciates diverse stakeholder interests.
- Inclusion of broader value drivers in the assessment to help manage evidence uncertainties.
- Establishment of risk-sharing agreements with conditional criteria, predetermined performance targets and exit points to adequately allocate risk across relevant partners.
- Development of frameworks, processes, policies and infrastructure for data collection in real-world settings to enable post-market reassessment and pricing negotiation, potentially supported by an independent third party.
- Harmonization and collaboration across HTA agencies and Payers across jurisdictions to enable sustainable healthcare systems and equitable access to patients.

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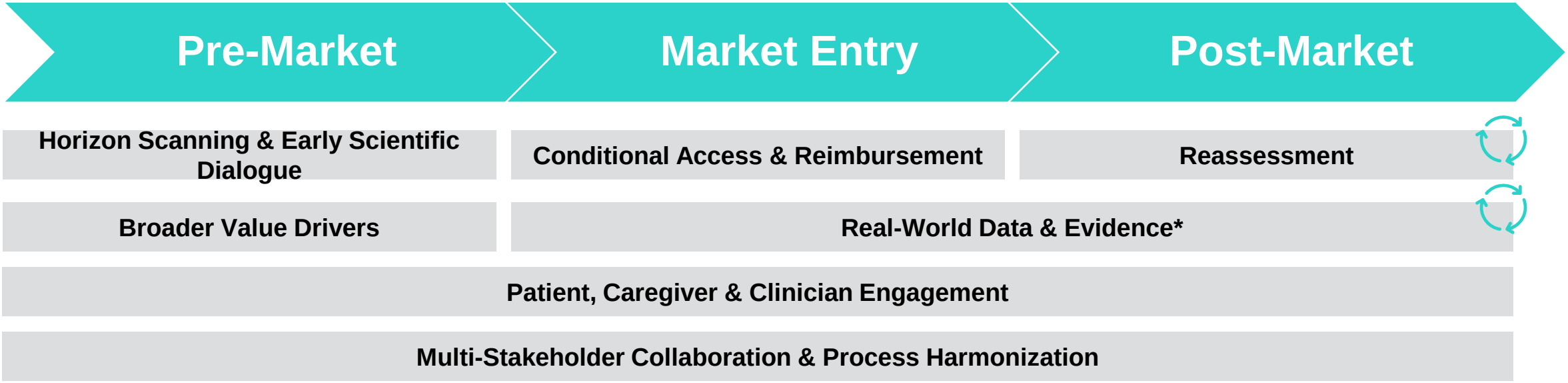
High-Level Framework

A life cycle HTA framework will empower stakeholders to better manage the uncertainties and reduce the risks associated with new precision therapeutics.



Indicates an iterative step that may take place more than once during the life cycle.

* Real-World Data (RWD): Data collected during the routine delivery of health care; Real-World Evidence (RWE): Evidence derived from the analysis of real-world data.

Poll Question 1

Rank the pillars of the proposed life cycle HTA framework in terms of importance to overcoming the challenges of assessing precision oncology therapeutics:

- Horizon Scanning & Early Scientific Dialogue
- Broader Value Drivers
- Conditional Access & Reimbursement
- Real-World Data & Evidence
- Reassessment

Poll Question 2

One key recommendation emerging from our discussions was the use of an independent multidisciplinary third party (e.g. academic centre of excellence) to advise HTA bodies and Payers on overall policies and pricing strategies, as well as to collect, review and report on outcomes to guide specific technology assessments.

To what extent do you agree that this type of an approach would help us to overcome some of the challenges of assessing precision oncology therapeutics?

- Strongly Agree
- Agree
- Neutral
- Disagree
- Strongly Disagree

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