Use Experience of Real World Evidence in the Actual Review

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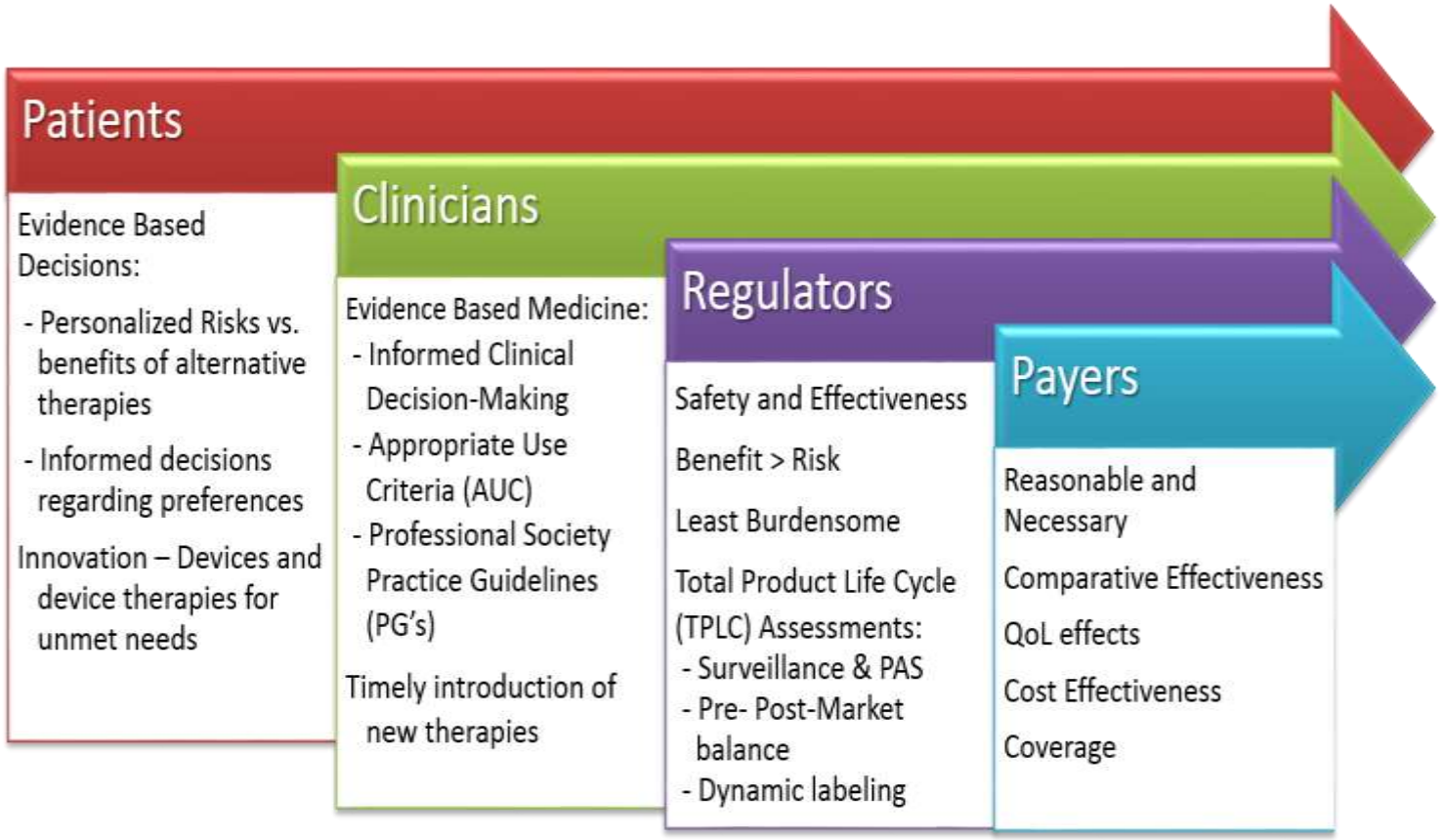
Clinical Evidence Generation

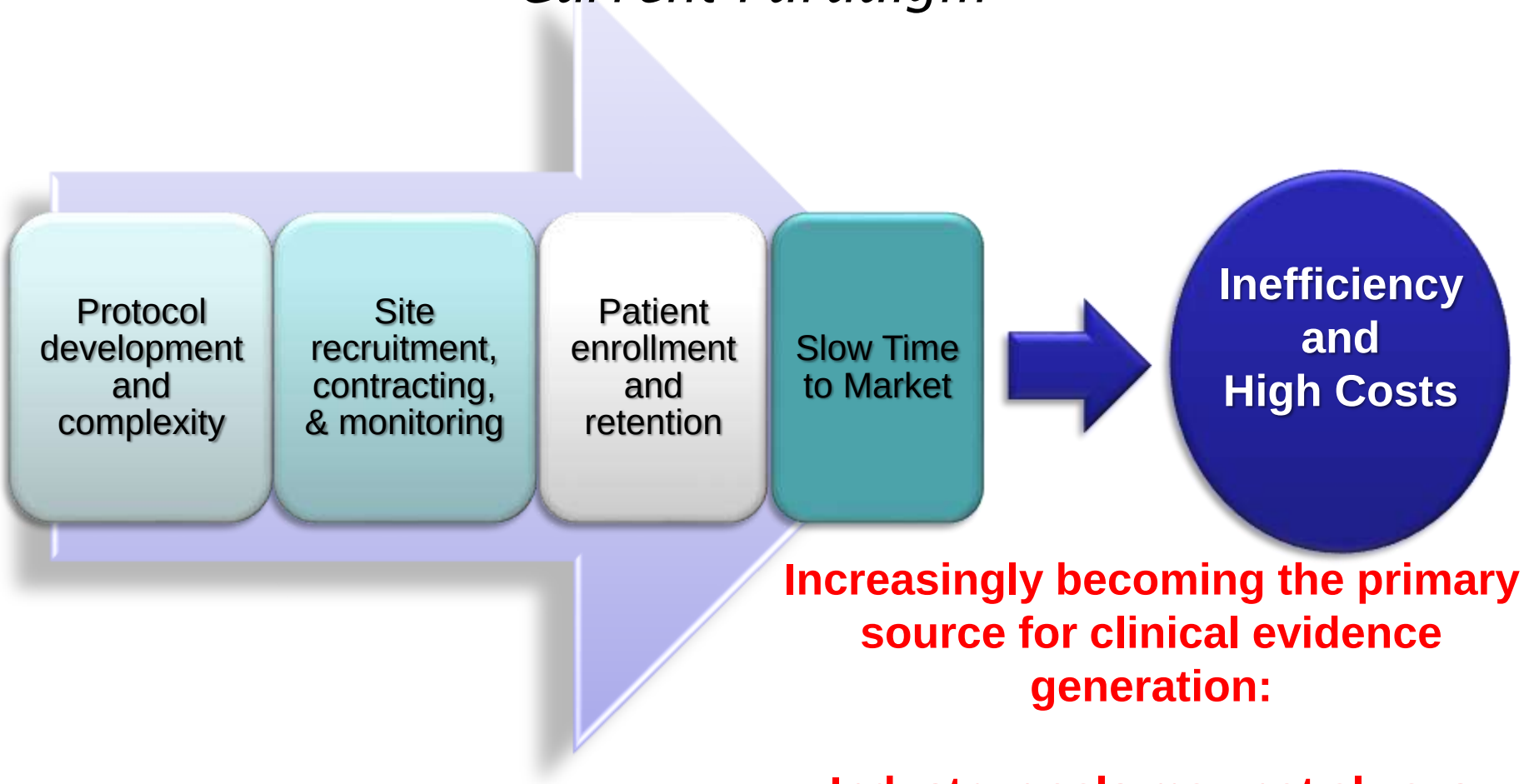
Current Paradigm



Appropriate, Timely and Generalizable Evidence For Informed Decisions

Clinical Evidence Generation

Current Paradigm



Increasingly becoming the primary source for clinical evidence generation:

Industry goals may not always align with clinical needs

Regulatory Considerations for Using Real-World Evidence

- Data source, relevance, reliability, quality, completeness, bias
- Demonstrate reasonable assurance of safety & effectiveness

When is Use of Real-World Evidence Appropriate

- Expansions of Indications
  - Increased indicated lesion length for the Zilver DES and Lutonix DCB
  - Expanded lesion type to include in-stent restenosis for In.Pact Admiral DCB and Lutonix DCB
- Post-approval surveillance
  - Evaluate longer term outcomes
  - Evaluate outcomes in US patients

Pathway for Success

- Pre-Submission to discuss a prospective analysis plan
  - Identify analysis type (e.g., propensity matching)
  - Identify confounders/covariates, appropriate endpoints
  - Determine methods to reduce bias

  → Build confidence in the SAP
- Follow the plan
- Submit supplement

Thank you!