



PHUSE US Connect 2026:
PD21

*Bridging Analysis to Strategy:
A Transformative Role of
Statistical Analyst in Drug
Development*



Lingsong Yun

25Mar2026





Outlines

Create map view outline (including time, # of slides, survey Q)

// Introductions (3 slides, 10mins): **survey Q1**

// Evolution of statistical programming and drug development

// SA role in real-world setting

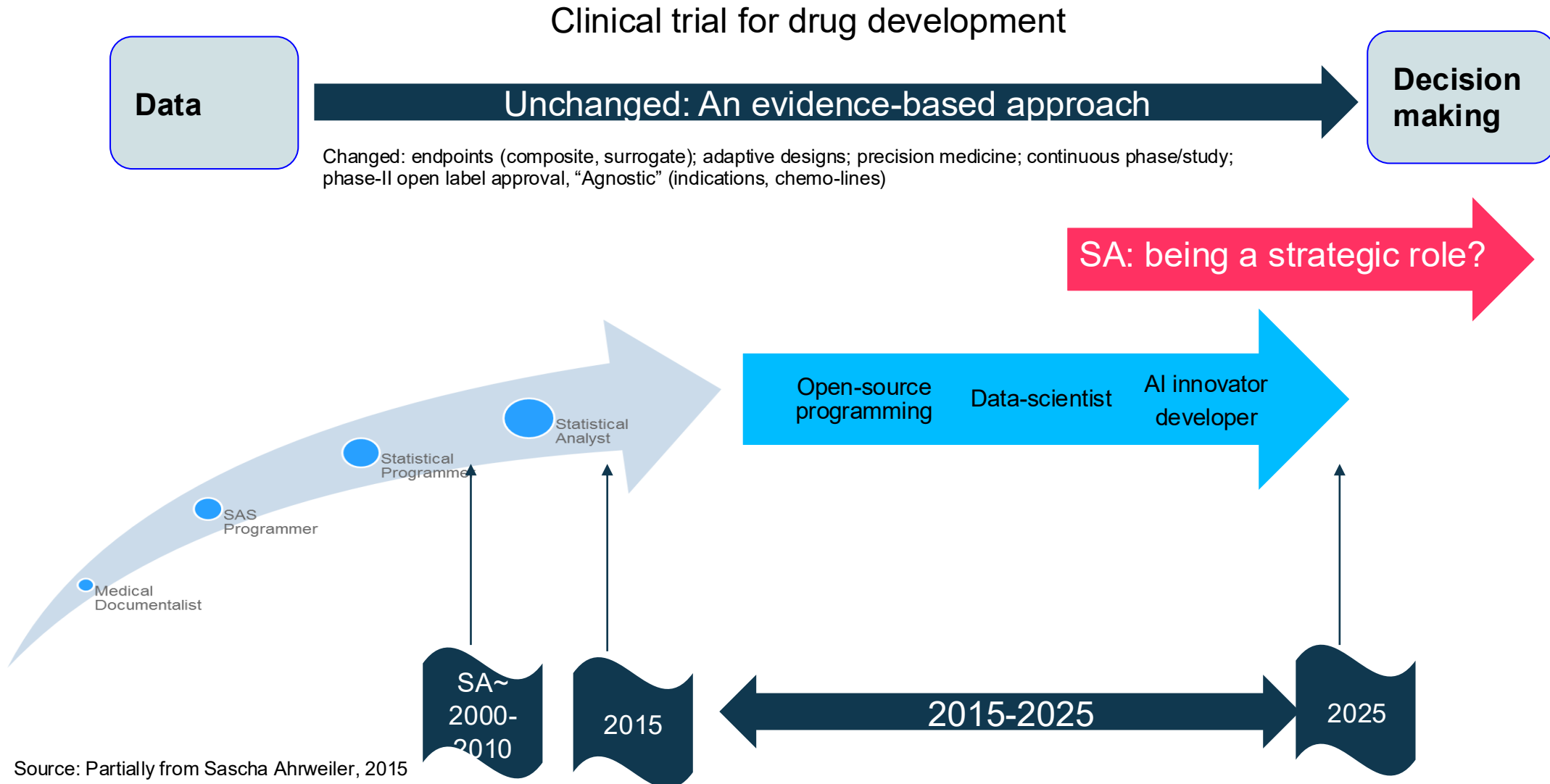
// Case study: a hybrid SA project in target therapy oncology (3 slides, 10 mins)

// Outcomes: bridging analysis to strategy (2 slides, 8mins)

// Analytics implementation: testimony and stories (8mins) : **survey Q3**

// Conclusions/takeaways (2mins)

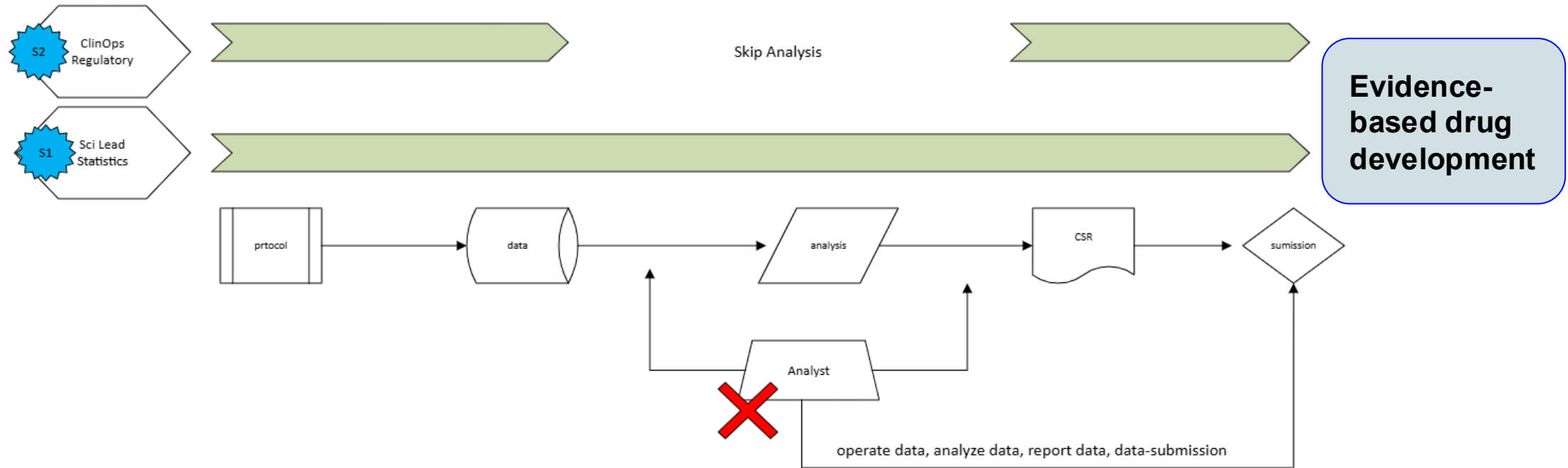
Statistical Analyst (SA) role changes



Source: Partially from Sascha Ahrweiler, 2015

Strategic roles in clinical trial development

Is analyst a strategic role in clinical trial development?



How bridging analysis to strategic role?

Analysis strategy/execution Data interpretations



Statistical Analyst role in real-world settings

Is real-world SA reflecting emerging trends in pharmaceutical

// Combined responsibilities in real-world

// Study design

// Analysis: strategy and execution

// Data activities

// Decision supports

// Less focused:

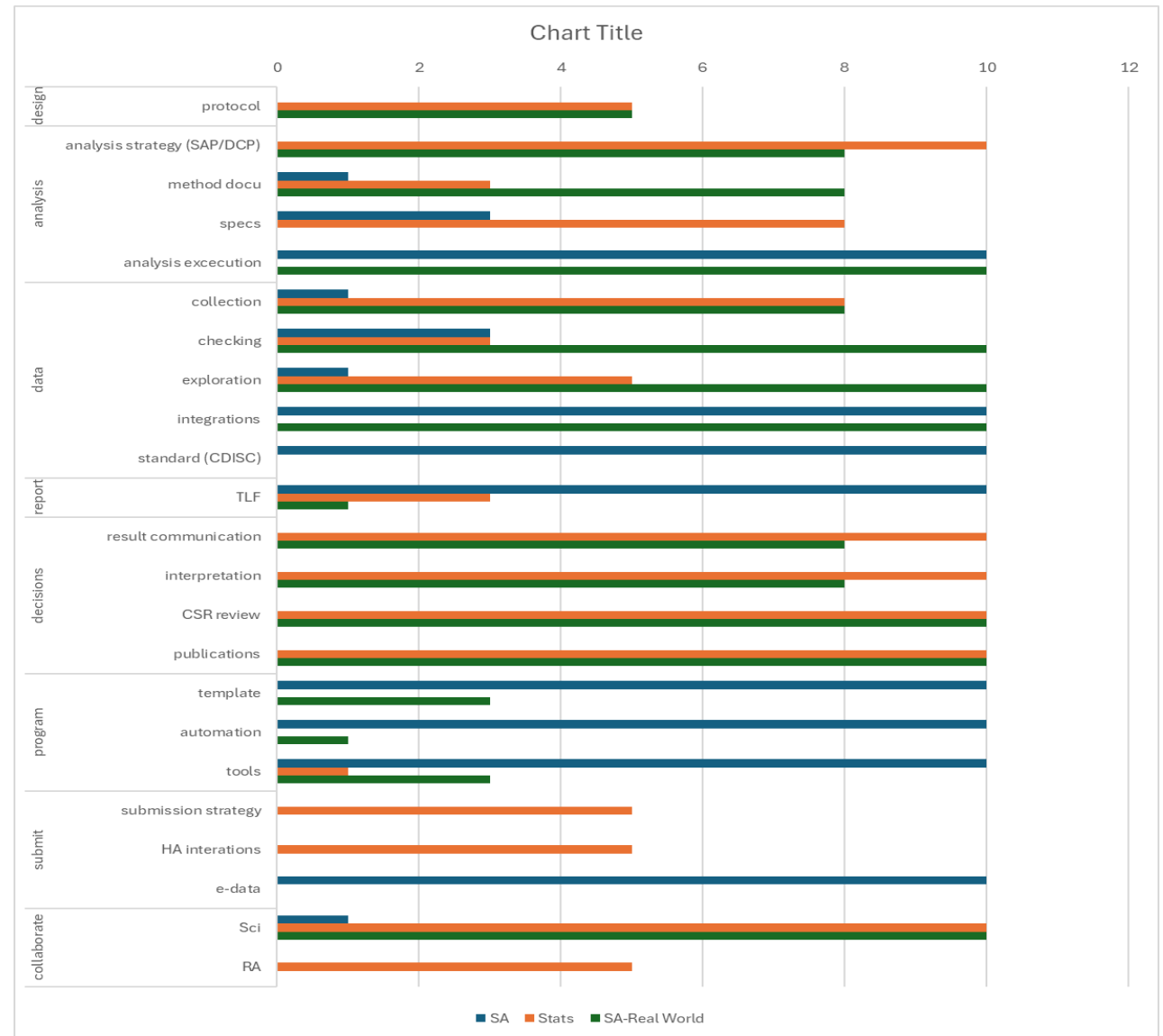
// Standardized programming

// Reporting

// Data package for submission

Source organizations evaluated:

- Institute for Clinical Evaluative Sciences (ICES)
- Cancer Care Ontario
- Canadian Institute for Health Information
- University Health Network

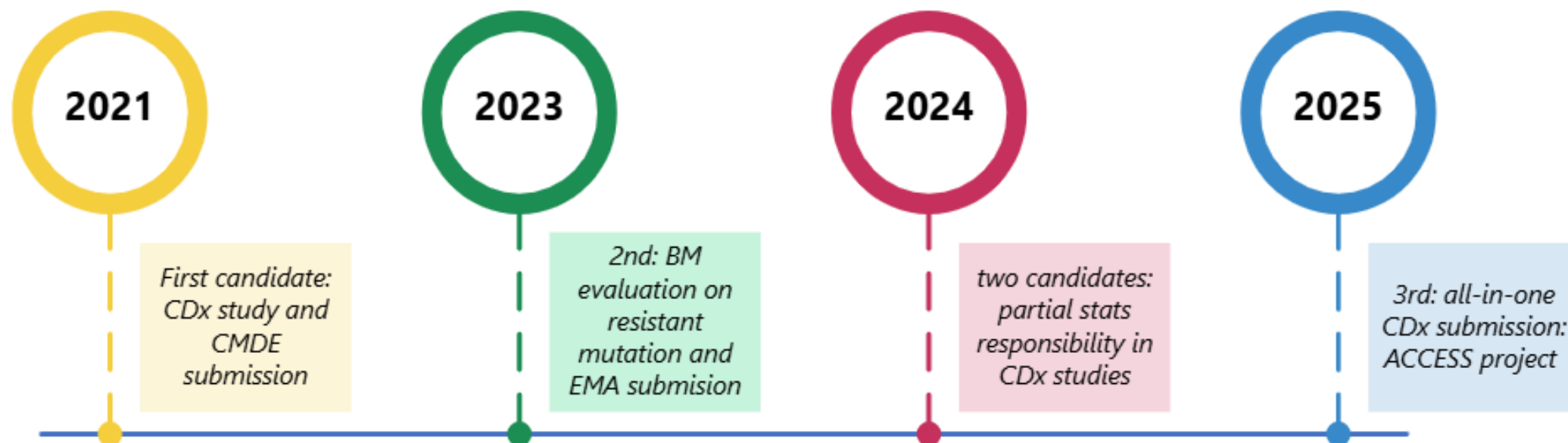


Case Study 1 - Design: A hybrid SA project in Target Therapy

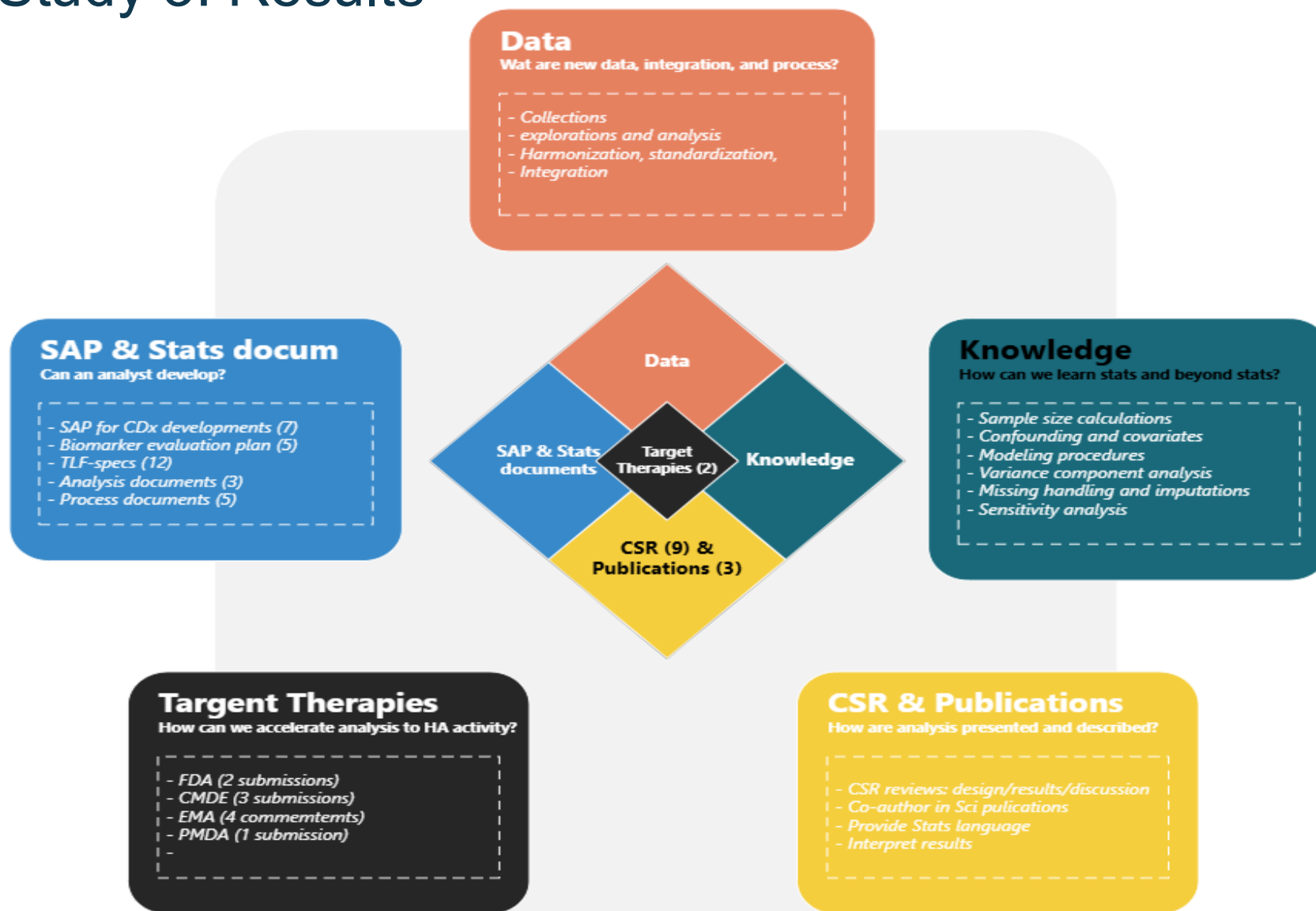




Case Study 2 – Candidates



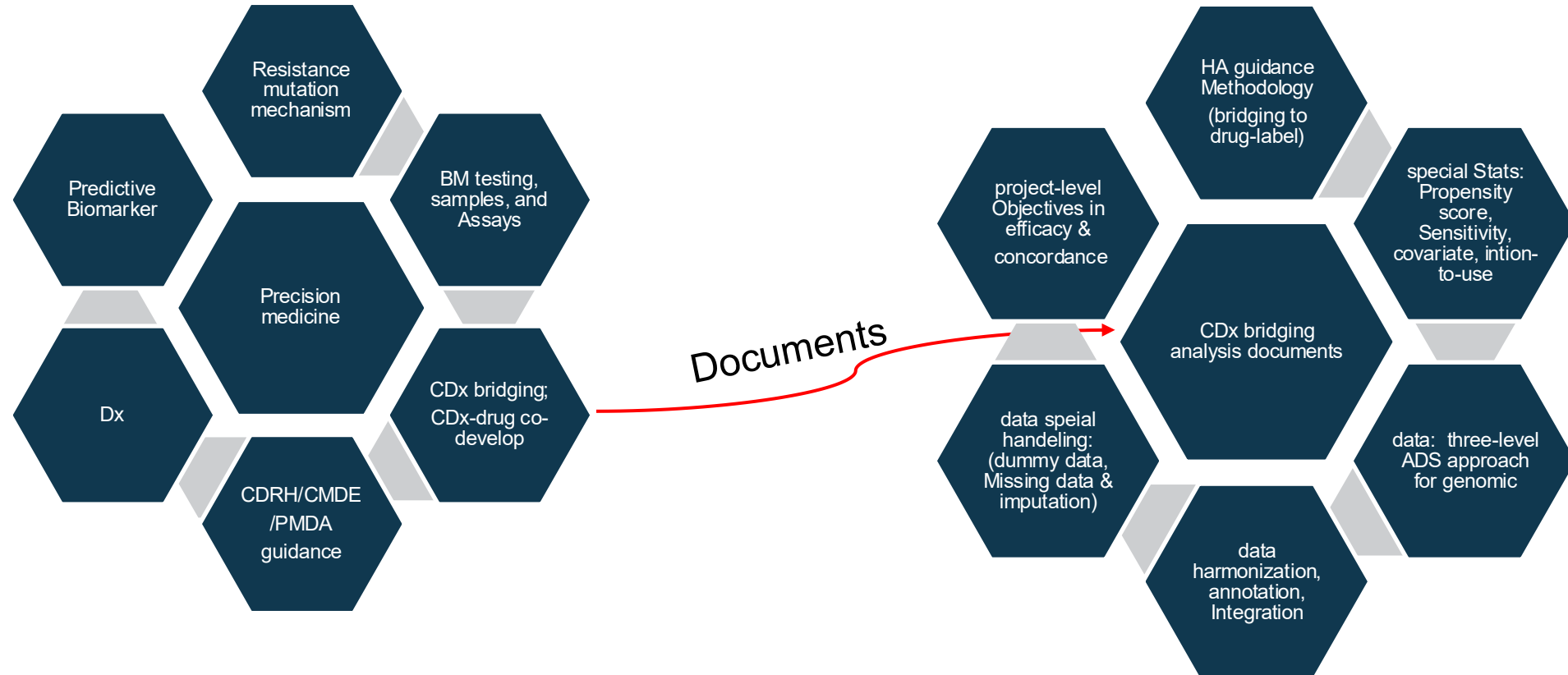
Case Study 3: Results





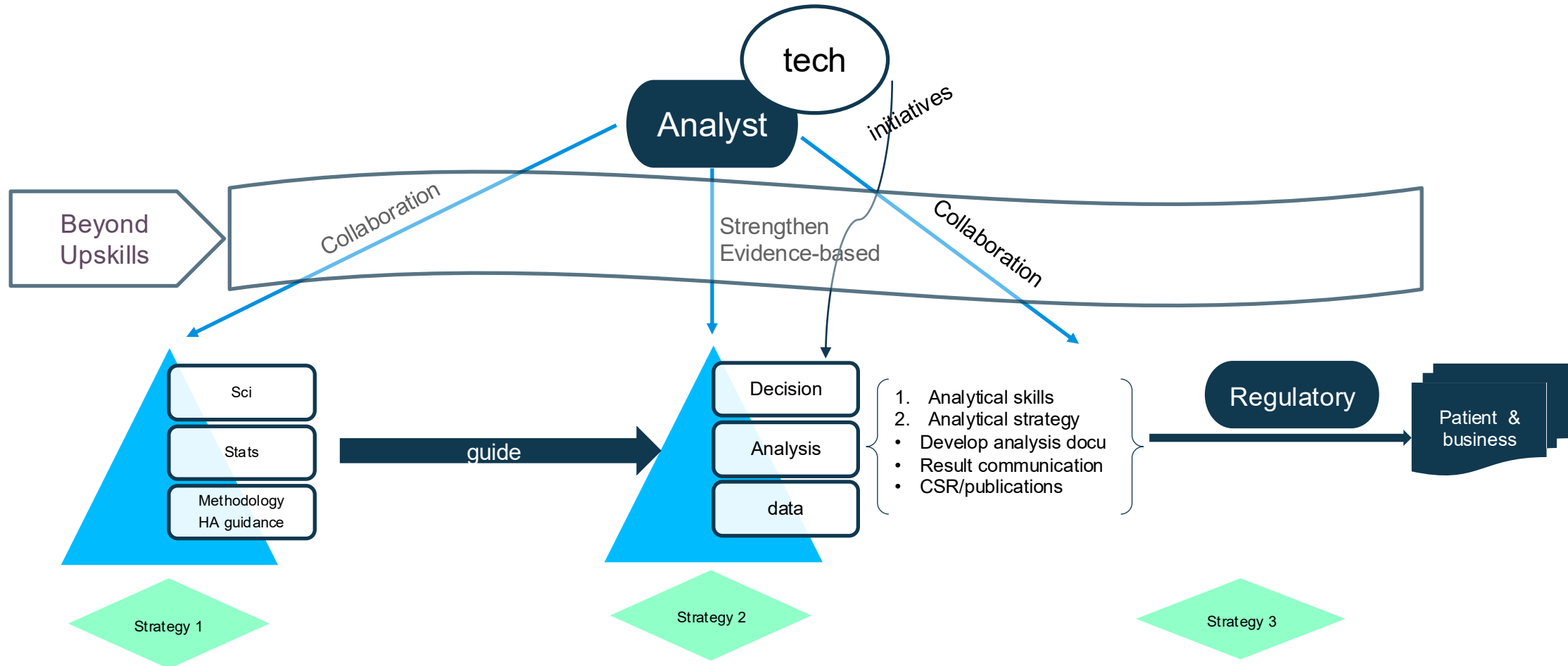
Case Study 4: Develop Analytical Documents

Biomarker and CDx

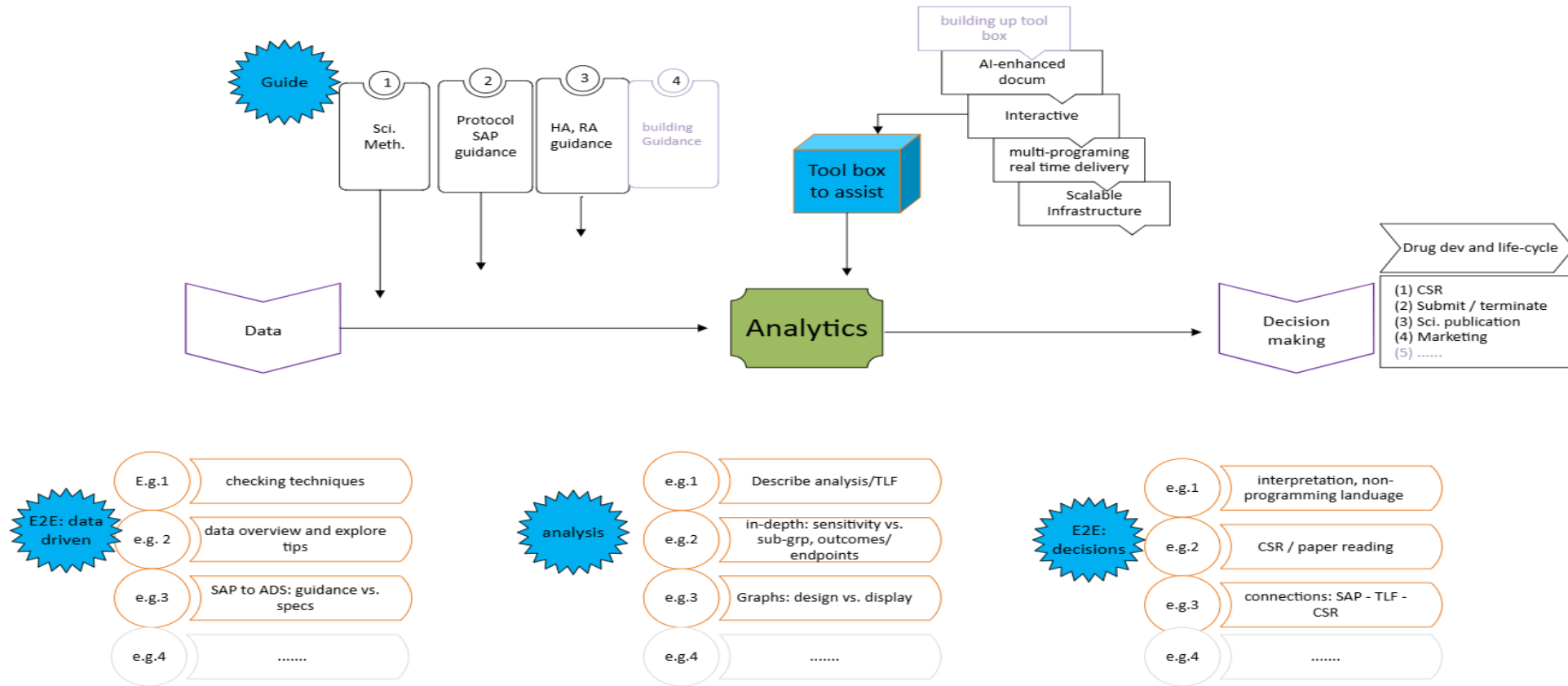


Outcome 1: Extended Strategic Analytical Mindsets via Analytics

Extended, beyond, upskilled



Outcome 2: Methodology-Data-Analysis-Decision Foundation



Note: re-design: 'guide' also in analysis-decisions, move 'tool box' to assist all other 4-components; provide recommendations (maybe in a different slide, see the draft in a paper)

Knowledge: in guide, analysis, decision components

Analytics Community: Enhance analytics framework and build analytics guidance

Capability Extensions

Ask these questions

Data-driven analytical foundation:

- How do we examine relationships within and across studies, compounds, or therapeutic areas?
- Do we systematically assess missing data patterns?
- What data checking, overviewing, and exploration development?
- How do we assess and support completeness of data?
- Can we explore new or external data sources and existing clinical trial databases?

Analysis and analytical strategy:

- Can we clearly describe the study SAP, including its analytical objectives and rationale?
- Can we articulate the analyses that are implemented and explain how they address study questions?
- Can we describe the purpose and interpretation of key tables and figures?
- Can we share in-depth analytical knowledge related to specific endpoints, health outcomes, novel study designs, or uncommon analytical approaches?
- Can we define and negotiate top-line result TFLs based on analytical objectives rather than template defaults?
- Can we design meaningful graphical data displays rather than focusing solely on their technical creation?

Methodological guidance and analytical continuity:

- Do we develop analytical guidance documents for studies, compounds, or therapeutic areas?
- Can we develop analysis datasets based solely on prescriptive specifications?
- Can we provide analytical overviews that support preparation?

Decision support and regulatory strategies:

- What are the methodological expectations of health authorities in specific therapeutic or scientific contexts?
- Which TFLs are included in clinical study reports and scientific publications, and what analytical questions do they address?
- What discussions, interpretations, and conclusions are ultimately presented in CSRs and publications, and how are analytical results translated into decision-relevant narratives?

❖ Health authority and evidence strategy

- ▲ • What are the key health authority considerations for an indication-agnostic defining the target population, strength of evidence across tumor types (confirmatory evidence)?
- What are typical regulatory expectations for tumor-agnostic claims regarding effect across tumors?
- Under what conditions might a successful Phase II study support multiple second-line or support regulatory decisions, and what additional evidence is needed?
- When could ORR be considered sufficient for an accelerated pathway, need for Phase III confirmatory evidence?

❖ Endpoints, efficacy evaluation, and interpretation

- For a composite endpoint (e.g., PFS; or composite cardiovascular events such as MI and stroke), what analyses are required to ensure interpretability (e.g., component-wise analyses, time-to-event methodology, competing risks considerations, and sensitivity analyses)?
- What additional analyses may be necessary to demonstrate robustness when composite endpoint components differ in clinical importance or frequency?
- What is an appropriate minimum follow-up duration to evaluate efficacy for a given oncology setting and endpoint, and how should maturity of data be assessed and communicated?
- How do follow-up requirements differ by endpoint type (e.g., ORR vs PFS vs OS) and treatment line?
- What constitutes a clinically meaningful and statistically interpretable objective response rate (ORR) in a specific disease context, and what thresholds (if any) are typically considered meaningful for decision-making?
- How should uncertainty (e.g., confidence intervals), durability of response, and response assessment criteria be incorporated into interpretation?



Example 1: Data Exploring

Survey

// How do you get these numbers in your practice?

// Total enrolled (ENRLFL)

// Total randomized (RANDFL)

// Total treated (TRT01FL)

// Total safety pop (SAFFL)

// Total efficacy pop (EFFFL)

Option 1:

Open the dataset (ADSL) and find the numbers

Option 2:

```
Proc freq data=adsl;  
  Tables ENRLFL;  
  Tables RANDFL;  
  Tables TRT01FL;  
  Tables SAFFL;  
  Tables EFFFL;  
Run;
```

Option 3:

```
Proc freq data=adsl;  
  Tables ENRLFL*RANDFL*TRT01FL*SAFFL*EFFFL/list missing;  
Run;
```



Example 2: Health Authority

Story: EMA oral presentation in 2019

Example 3: Learn from Reading (CSR and publications)

Story: EMA oral presentation in 2019



Takeaways:

- // Build strategic mindset and methodology-data-analysis-decision foundation
- // Develop analytical guidance documents (methodology, algorithm) in addition to specs
- // Learn from scientific publications (CSR, posters, proceedings, journals) then guide TLF
- // Upskill being analytical
- // Collaboration extensions with strategic stakeholders
- // Communicate with common literacy language instead of programming, variable names, data domain names



Q&A

