TuftsMedicine
Tufts Medical Center

Metrics for Evaluation Thresholds & Reimbursement for Incentive Correlation across Stakeholders (METRICS) Team

Team Meeting

November 15, 2022

NEWDIGS

METRICS Team Meeting Participants

Name	Organization	
Diana Frame	NEWDIGS	**METRICS Team Co-lead & Meeting Facilitator**
Gail Ryan	Point32	**METRICS Team Co-lead & Meeting Facilitator**
Jamie Foley	Takeda	**METRICS Team Co-lead & Meeting Facilitator**
Nash Guerrier	NEWDIGS	Scribe
Dasha Cherepanov	Takeda	
Kaitlin Gately	Point32	
Mark Lin	Takeda	
David Strutton	Merck	
Eric Small	*NEWDIGS*	*Voting Tally Official*

Team Meeting & Report Out Timing

1:45-3:15 pm Team Meeting

- 10 minutes – Introductions and presenter selection
- 70 minutes – Discussion
- 10 minutes – Presentation coordination

Notes and instructions

- **Each team will need to pick a presenter for the Report Out session that follows the team meeting session. *Please do this first!***
- **Each team meeting will be facilitated by the Team Lead and have a pre-selected scribe(s).**
- **At 3:15 pm, please send the presentation to the email hyperlinked on the last slide.**

3:15-3:30 pm Break

3:30-4:30 pm Team Reports and Group Discussions

Per team:

- 10 minutes – report out
- 5 minutes – Q&A

Agenda

- Status Update
- Metrics & Measures Prioritization
  - Clinical Outcomes Measures short list
    - Presenter: Gail Ryan, Point32Health, and METRICS Clinical Outcomes Metrics subteam lead
  - Impact Metrics short list
    - Presenter: Jamie Foley, Takeda and METRICS Impact Measures subteam lead
- Discussion: Generalizable Process for Identification & Selection of Clinical Outcomes & Impact Metrics
- Time permitting: Discussion on Generalizability of Impact Metrics

Target Variables Selection

- **Filtering Step:** At Oct. 25th METRICS team meeting, two questions were considered for each of the short lists presented:
  1. Select the measure/metric that you think is most important for the NSCLC Case Study
  2. Select the measure/metric that you think is most feasible to implement in the NSCLC Case Study

- **Results**
  - **Clinical Outcomes Metrics:**
    - Median Overall Survival (OS)
    - Time to treatment failure
    - Median Progression Free Survival (PFS)
  - **Impact Measures:**
    - Time to treatment/"effective treatment”
    - Total cost of care

- In the context of our *Process*, our goal for today’s discussion is to complete the **Prioritization** step with the broader LEAPS multistakeholder collaborator community

Measures & Metrics Prioritization

Clinical Outcomes Measures

Measure #1: Median Overall Survival (OS)

Definition: The length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that half of the patients in a group of patients diagnosed with the disease are still alive.

Data Sources:

- Electronic Health Record (EHR; healthcare providers) – date of diagnosis; start/ end dates of therapy; medical status
- Pharmacy/medical claims (payers) – start of therapy; subsequent claims indicative of continued therapy and/or services
- Registries (developers) - comprehensive

Source: National Cancer Institute, from <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/median-overall-survival>

Clinical Outcomes Measures

Measure #2: Time to Treatment Failure (TTF)

Definition: Time to treatment failure (TTF) is defined as a composite endpoint measuring time from randomization to discontinuation of treatment for any reason, including disease progression, treatment toxicity, and death.

Data Sources:

- EHR (healthcare providers) – start/end dates of therapy, medical status, rationale for D/C, e.g., progression, toxicity
- Pharmacy/medical claims (payers) – start of therapy, estimated end date of therapy
- Registries (developers) - comprehensive

Source: FDA's Oncology Center of Excellence, Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics, Guidance for Industry. 2018.

Clinical Outcomes Measures

Measure #3: Median Progression Free Survival (PFS)

Definition: The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse.

Data Sources:

- EHR (healthcare providers) – start/end dates of therapy, disease progression medical status
- Pharmacy/medical claims (payers) – start of therapy, estimated end date of therapy, subsequent claims indicative of continued therapy and/or services
- Registries (developers) - comprehensive

Source: National Cancer Institute, from <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/progression-free-survival>

Complete Prioritization Voting for Clinical Outcome Measures

Process:

- Everyone will receive 5 votes to allocate across the 3 measures based on your determination of how they should be prioritized.
- There will be 3 ballot boxes on a table for everyone to place their tickets into – you can allocate all your votes for 1 measure or a combination across more than 1 measure.

Median Overall Survival (OS)

Time to Treatment Failure (TTF)

Median Progression Free Survival (PFS)

Impact Metrics

Metric #1: Time to treatment/"effective treatment”

Definition: Time from symptom onset to effective first treatment.

- We would like to explore this metric in 2 ways: (i) Time from symptom onsite to effective treatment date, and (ii) Time from diagnosis (i.e., NSCLC diagnosis) to first treatment.

Measurement:

- Assumptions:
  - EHR/claims data available and captures the patient treatment journey reasonably well.
  - Time from first visit for associated condition to treatment without short-term switch indicative of either significant side effects or lack of efficacy.
    - For example, in NSCLC this might be a switch to another treatment without 3 months of therapy being dispensed.

Impact Metrics

Metric #2: Total cost of care

Definition: Total cost of an episode of care for a patient

It would be helpful to aggregate costs in at least 4 ways:

- Total of all treatment-related costs (for discussion - i.e., parking, travel, patient and caregiver opportunity costs, etc.)
- Total of all medical costs
- Total of costs directly related to the diagnosis and treatment of the condition (i.e., NSCLC)
- Total of costs related to complications of the condition (i.e., for NSCLC: Anemia, fatigue, nausea, and other condition/treatment-related side effects)

Measurement Assumptions:

- The goal of the model is not to identify differences in charges for the same event, but to look overall. If this is the case, events should be identified, and costs assigned to them that are already standardized.
- Patient total cost of care will be represented in aggregate or average, and the goal will be sub-group assessments.
- Data may include Claims/EHR data, wearables or cell phone data that tracks location, socioeconomic data, survey data, chart reviews (Scope of inclusions should be discussed with the modelling team)
- Scope of what events are considered in the episode of care is important. Given this metric is intended to be impactful to a multi-stakeholder group, a broader capture may be better.

Complete Prioritization Voting for Impact Metrics

Process:

- Everyone will receive 5 votes to allocate across the 2 measures based on your determination of how they should be prioritized.
- There will be 2 ballot boxes on a table for everyone to place their tickets into – you can allocate all your votes for 1 measure or a combination across both measures.

Time to treatment/"effective treatment”

Total cost of care

LEAPS Generalizable Process for Identification & Selection of Metrics

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LEAPS Process and Use Case

Domain	Proposed LEAPS Process	ICIs in NSCLC Use Case*
Scope specification	Align **SCOPE**: -The setting(s) in which the outcomes sets are to be applied	US real-world care system
	-The health condition(s) covered by the outcomes sets	Advanced or metastatic non-small-cell lung cancer (adv/met NSCLC)
	-The population(s) covered by the outcomes sets	Adult adv/met NSCLC patients (regardless of insurance coverage, practice setting, or US region)
	-The intervention(s) covered by the outcomes sets	Immune checkpoint inhibitors (ICIs)
Stakeholders involved	**INVITE**: Apply LEAPS stakeholder mapping process to identify those who will use the outcomes sets in practice, RWD analysis, or coverage decisions	Patient, clinician, payer, developer, and analytics team representatives
Consensus process	**GATHER** initial list of outcomes considering views of all stakeholders - Collection process: should include multi-stakeholder meeting(s), review of existing literature (both trials and RWE studies)	a) Clinical outcomes: initial list developed at multi-stakeholder Design Labs, and by Clinical Outcomes subteam, informed by lit review b) Impact Metrics: initial list developed by Impact Metrics subteam, informed by lit review
	FILTER initial list of metrics for feasibility / practicality / duplication - Describe (implicit and explicit) criteria used to create "short list" - Note all measures ranked as important by stakeholders, but not included for practicality / lack of data	Analytics/modeling team; patient, clinician, payer, and developer representatives
	PRIORITIZE A scoring process and consensus definition is used, described, and refined based on continuous learning process - Scoring and consensus process: modified Delphi, ranking survey, other? - Nominate proxy measures for important but technically infeasible outcomes	a) Clinical outcomes: initial list prioritization by the ICIs in NSCLC pilot team; voting exercise at Design Lab b) Impact Metrics: initial list prioritization by the ICIs in NSCLC pilot team; voting exercise at Design Lab
	Establish **THRESHOLDS** for action - Thresholds for decision-making (e.g., incremental difference needed) to be sought for each stakeholder category - Care is taken to avoid ambiguity of language used in the list of outcomes	Whiteboarding session at Design Lab with representative group of stakeholders

** After scope specification and stakeholder mapping, the consensus process is applied to both a) Disease-specific Clinical Outcomes and b) Systems-level Impact Metrics*

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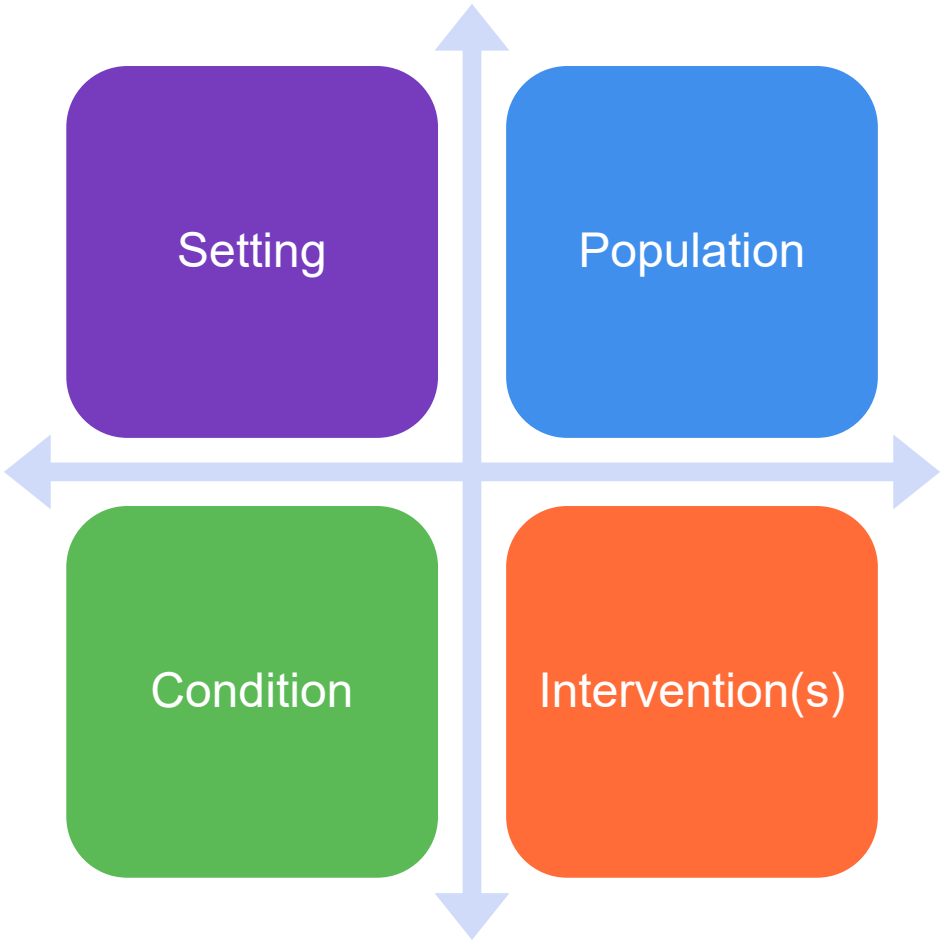
Scope

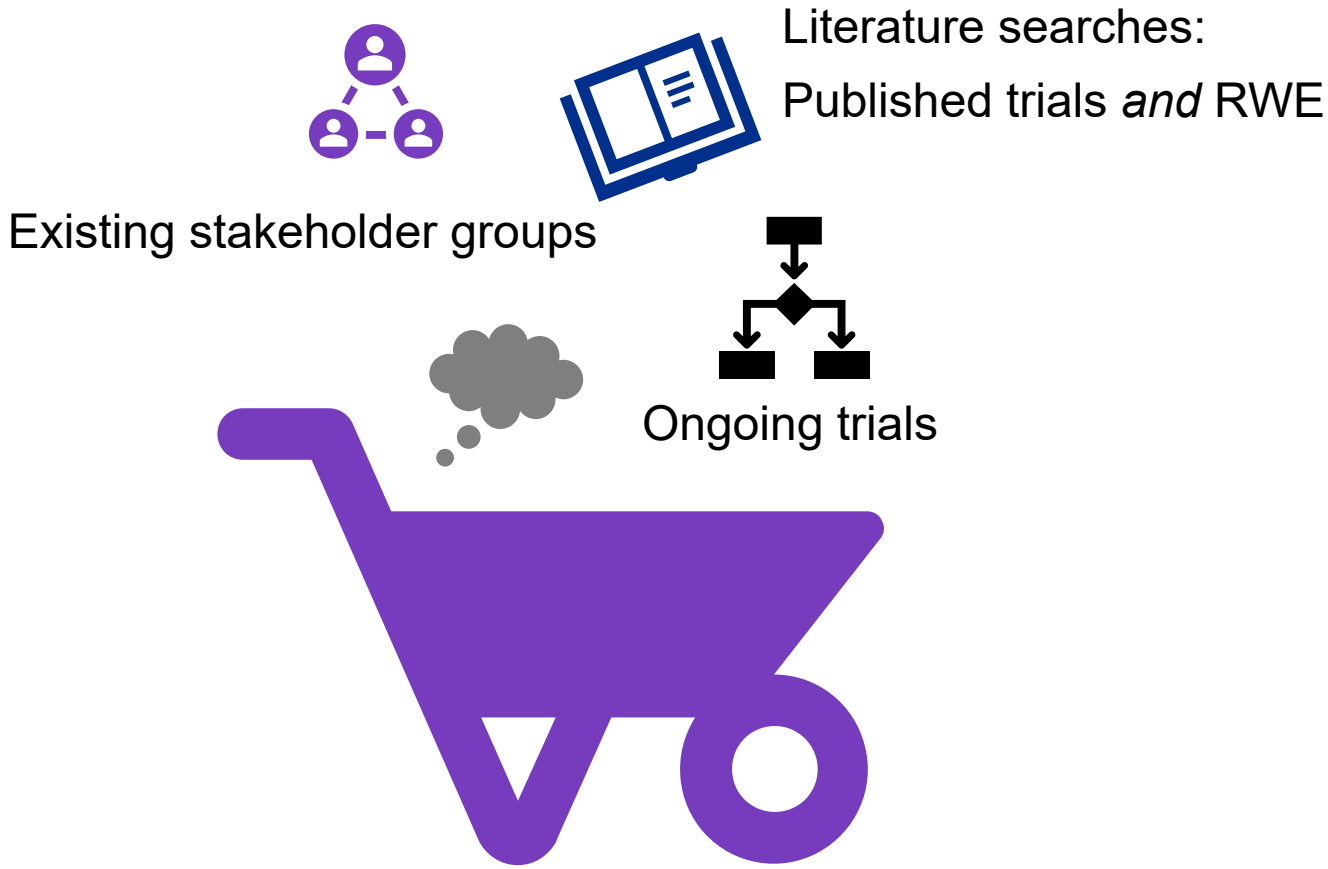


Invite

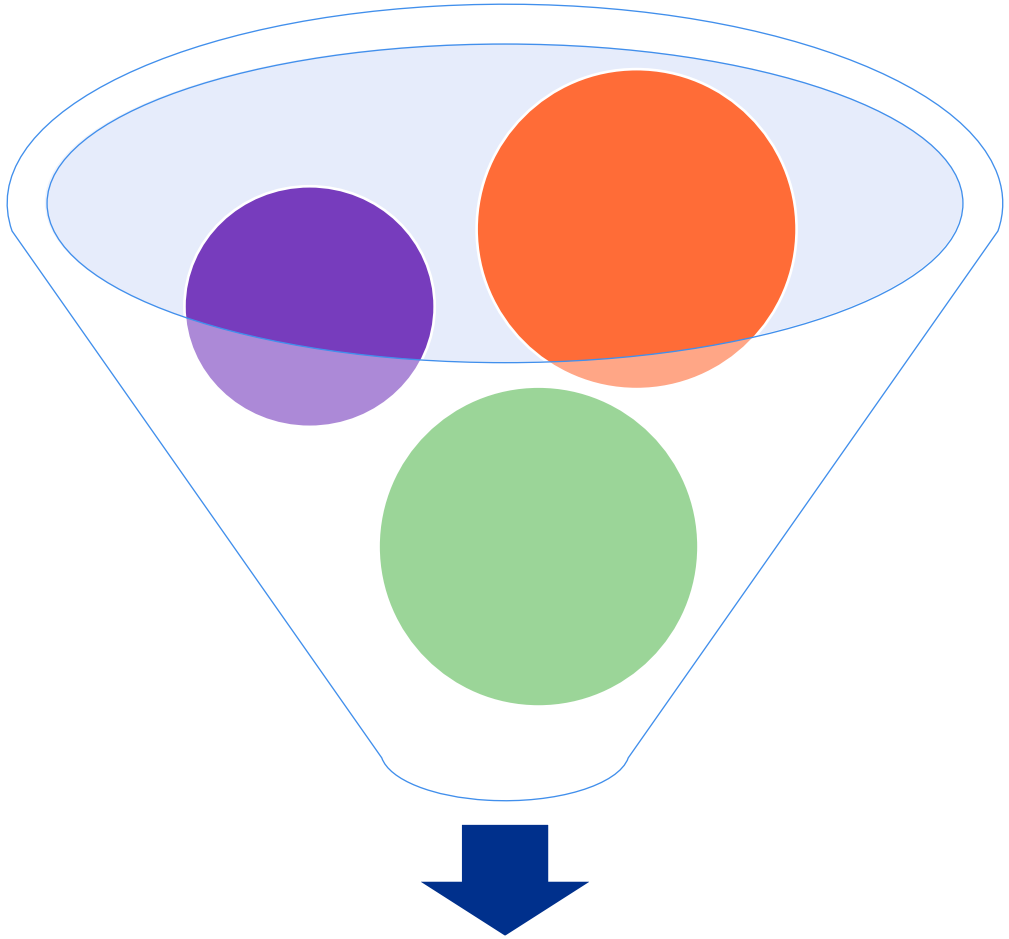
"In an ideal world": Apply full LEAPS stakeholder mapping process

For this pilot case: we convened 2 multi-stakeholder Design Labs reaching out to stakeholders with interest in oncology topics…

Gather possible metrics/measures



Filter



Short list of 3-5 measures

Prioritize

Most modified Delphi efforts include at least one round of group voting - for this pilot, proposing we use *cumulative voting* and we conduct this exercise at the November Design Lab (Day 1 breakout)

- Each participant gets the same number of "vote markers" and can distribute them in any way - all votes to one Clinical Outcome, or split between several outcomes on the "short list"
- Polling results are blinded until voting is complete
- The total number of votes received for each outcome is tallied and the Clinical Outcome with the most votes is nominated for use in the analytic model (or two? If the vote is tied / very close?)
- Repeat the same process for the "short list" of Impact Metrics

Determine Thresholds for Action

Other Discussion Topics (time permitting)

Testing the generalizability of the impact metrics to other therapeutic areas

- Ex. diabetes, auto-immune diseases, MS, asthma

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