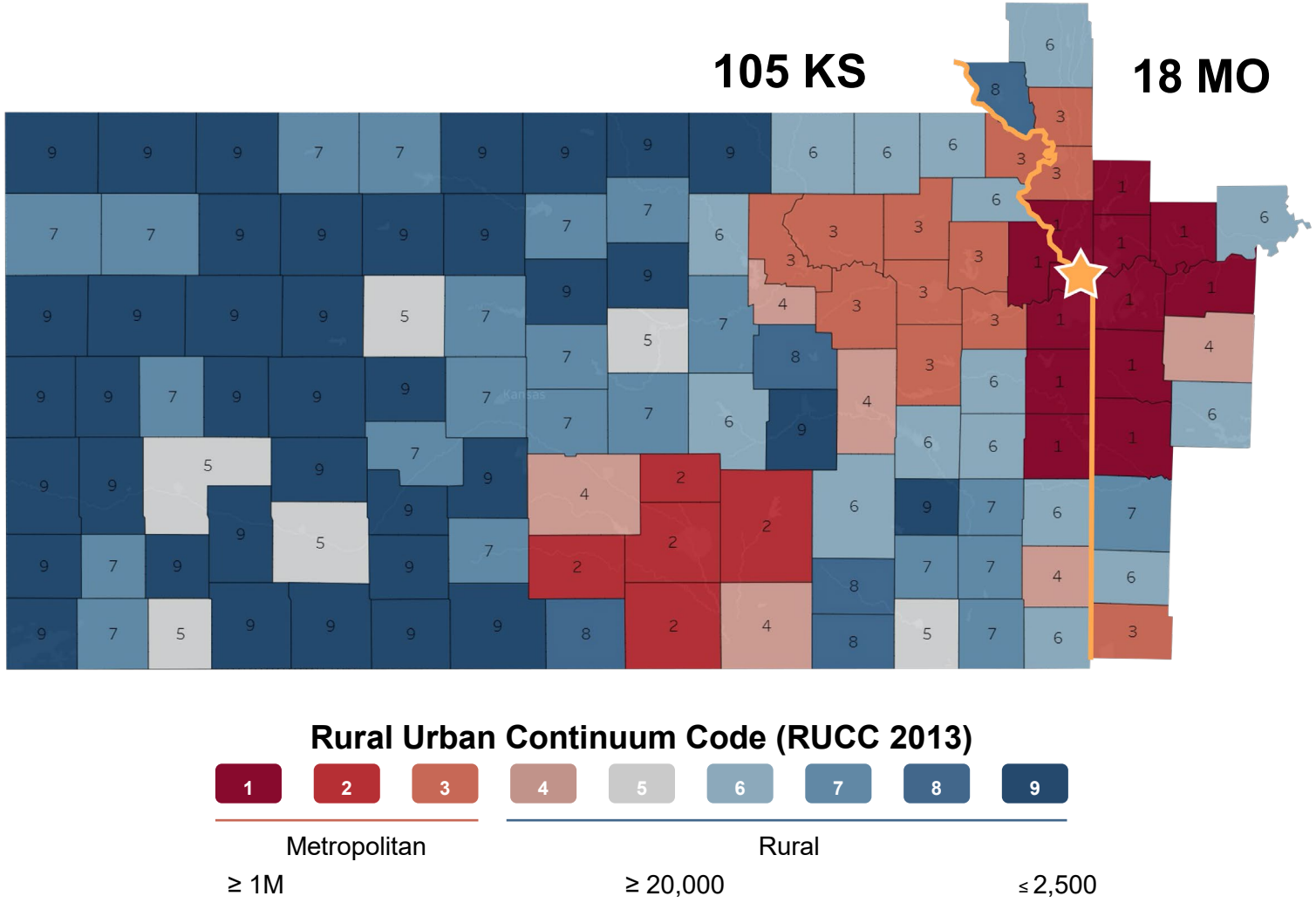
Bridging Gaps in Cancer Care Access Across Catchment Areas

Dinesh Pal Mudaranthakam, PhD, MBA, MS
Assistant Professor, Department of Biostatistics & Data Science
Director, Research Information Technology, *University of Kansas Medical Center*
Co-Director, Biostatistics & Informatics Shared Resource
Co-Director, Investigator-Initiated Trials, *The University of Kansas Cancer Center*
Assistant Director, Neuro Imaging Core, The KU Alzheimer's Disease Research Center

The University of Kansas Cancer Center - COE

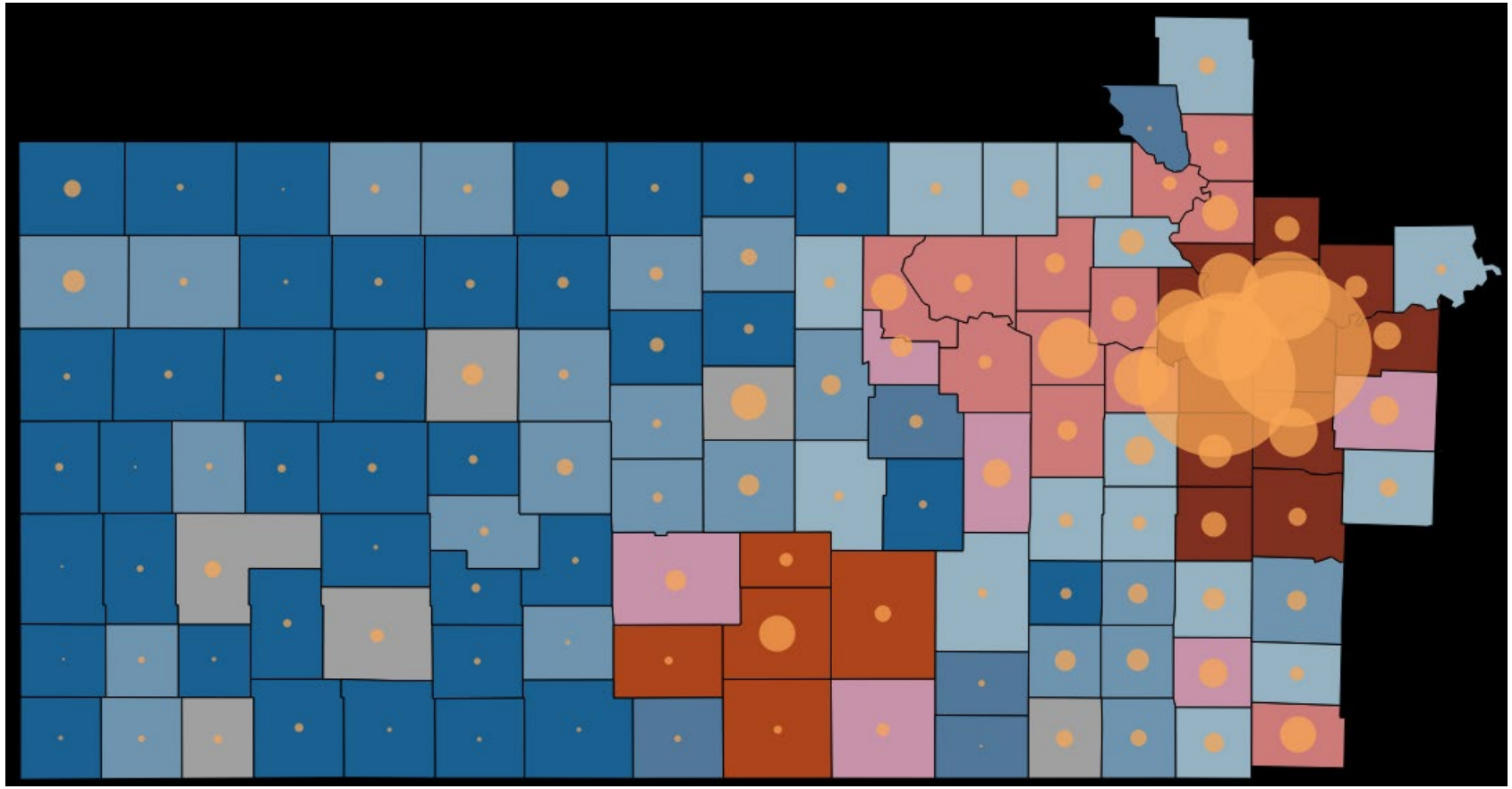
- 123 Counties
- 94% of KUCC patients
- 93 Counties Rural

  RUCC 4-9 (76%)

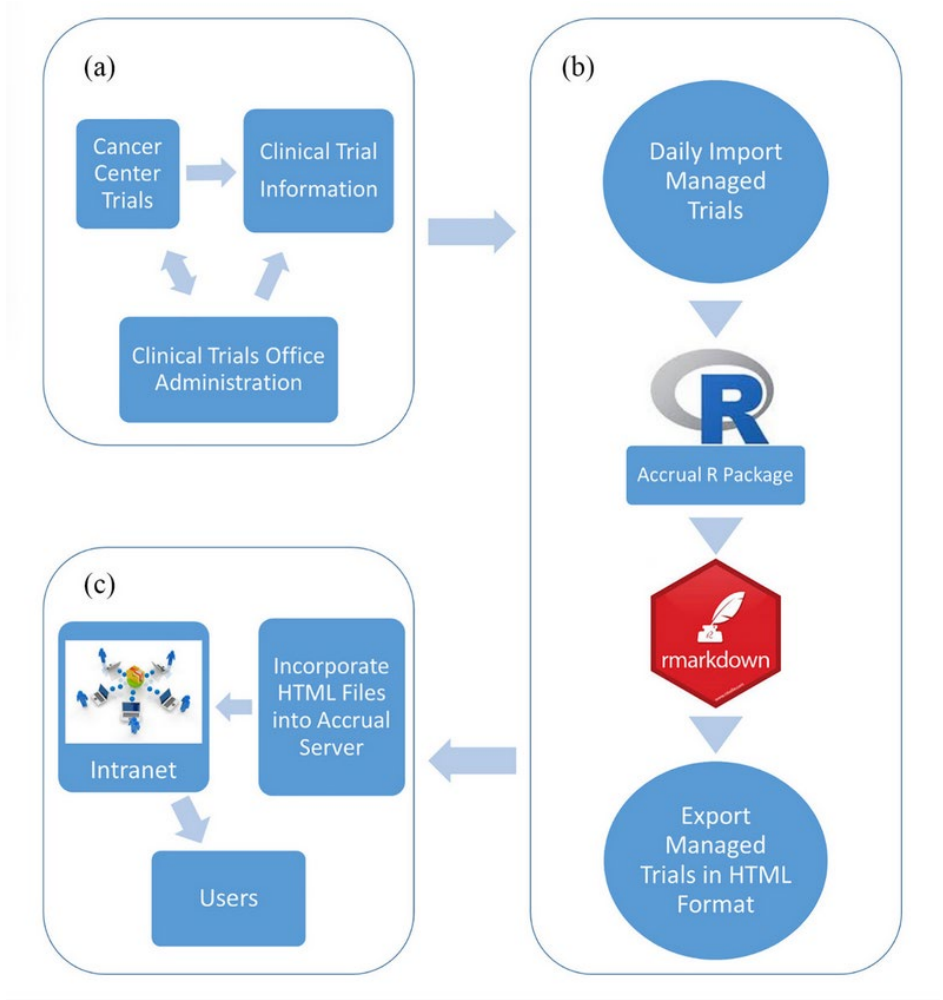


KUCC – Clinical Trial Portfolio

- 500-600 Active Studies
- 180-200 Active Enrolling Studies
- Masonic Cancer Alliance



Accrual Prediction App



Reference: Liu J, Wick JA, Mudaranthakam DP, Jiang Y, Mayo MS, Gajewski BJ. Accrual Prediction Program: A web-based clinical trials tool for monitoring and predicting accrual for early-phase cancer studies. Clin Trials. 2019 Dec;16(6):657-664. doi: 10.1177/1740774519871474. Epub 2019 Aug 26. PMID: 31451012; PMCID: PMC6904514.

An Application for the Entire Clinical Trial Team

Trial Builder	• Modify an existing trial or build your own on with a step-by-step process.
Feasibility	• Population assessment (demographics, disease relevance, eligibility) to run successful trials • Trial criteria manipulation for clinical impacts.
NEW **Accrual Prediction** KU MEDICAL CENTER The University of Kansas	• Program predicts the successful patient enrollment for trials based on statistical analysis. • Informs decision making in the trials office and links to trial view to find more patients.
Trial View:	• Identify eligible patient cohorts for trials. Matches many patients to many trials. • Allows for insight into screening and enrollment for increased trial accrual.
Patient View	• Find trials patient is eligible for directly from your EMR. Matches 1 patient to many trials. • Allows for a deep dive into patient specific inclusion criteria at the point of care.
COMING SOON **Trial Performance** KU MEDICAL CENTER The University of Kansas	• Report on Key Performance Indicators (operational, financial, clinical). • Appealing to clinical research coordinators, managers, directors, PI's and C-Suite executives.

Accrual Prediction:
Forecasting Trial Success

- Completed Trial
- </= 30% chance of being late - not meeting accrual goals
- Between 30%-80% of meeting accrual goals
- >/= 80% of being late – not meeting accrual goals

Accrual Prediction | Dashboard | Audits | Setup

All Clinical Trials

Search | Filter

Accrual Health	Sponsor ID	Study Number	Diagnostic Working Group	Title	Principal Investigator	Statistician	Sample Size	Expected Duration (Months)	Start Date	Enrolled	Estimated End Date	Lower Bound	Upper Bound	Probability Late Accrual
🔴	12	20221385	Head and Neck Multiple	4101 (Autologous Selected and Expanded Tumor-Infiltrating Lymphocytes [TIL]) and Pembrolizumab in Patients with Advanced Solid Tumor Malignancies (STARLING)	Christian Simmons		24	36	2022-05-02	12	2026-09-04	9/5/2025	7/22/2028	99.95%
🔴	23	20231043	Breast	NRG-BR009: A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score	Bella Rivera		10	12	2023-08-29	6	2025-04-17	11/24/2024	5/24/2026	100.00%
✅	29	20231319	Lung Multiple Early Phase Clinical Trials (EPCT)	A Phase 1 Study Evaluating the Safety, Tolerability, and Efficacy of BL-B01D1 in Subjects With Metastatic or Unresectable Non-Small Cell Lung Cancer and Other Solid Tumors	Savannah Gray		10	60	2022-05-16	56	2024-09-30	NA	NA	Completed
✅	32	20210118	Breast	The CompassHER2 Trials (Comprehensive Use of Pathologic Response Assessment to Optimize Therapy in HER2-Positive Breast Cancer) CompassHER2 Residual Disease (RD), a Double-	Gabriel Russell		5	36	2022-12-06	6	2024-09-30	NA	NA	Completed

Accrual Prediction: (cont'd)

> The Study Number:

> The updated date is: **2025-03-21**.

This is an accrual analysis summary for Accrual Studies. Based upon the information that is entered in

The output show as following:

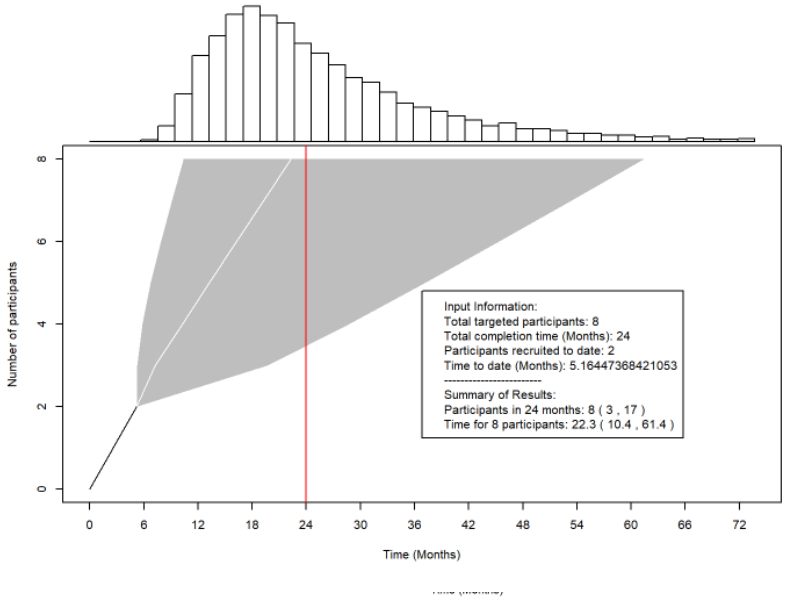
```
## STUDY_TITLE: An Open-label Phase I Study of  in Participants with Locally Advanced (Unresectable) or Meta
static Solid Tumor Malignancies with KRAS G12D Mutation
```

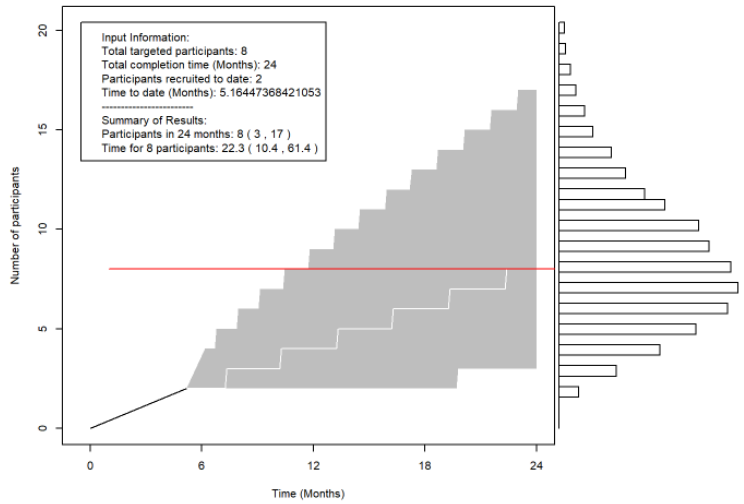
```
##                                                                    Study_Number||
##
##  N Prediction|| 95% CI Lower Bound|| 95% CI Upper Bound||
##              8                    3                   17
```

```
##                                                                    Study_Number||
##
##  T Prediction|| 95% CI Lower Bound|| 95% CI Upper Bound||
##    22.33 Months                10.4                61.42
```

In summary, the predictive completion date is 2026-08-24 with 95% credible interval (2025-08-27, 2029-11-25), based on the study activation date 2024-10-15.

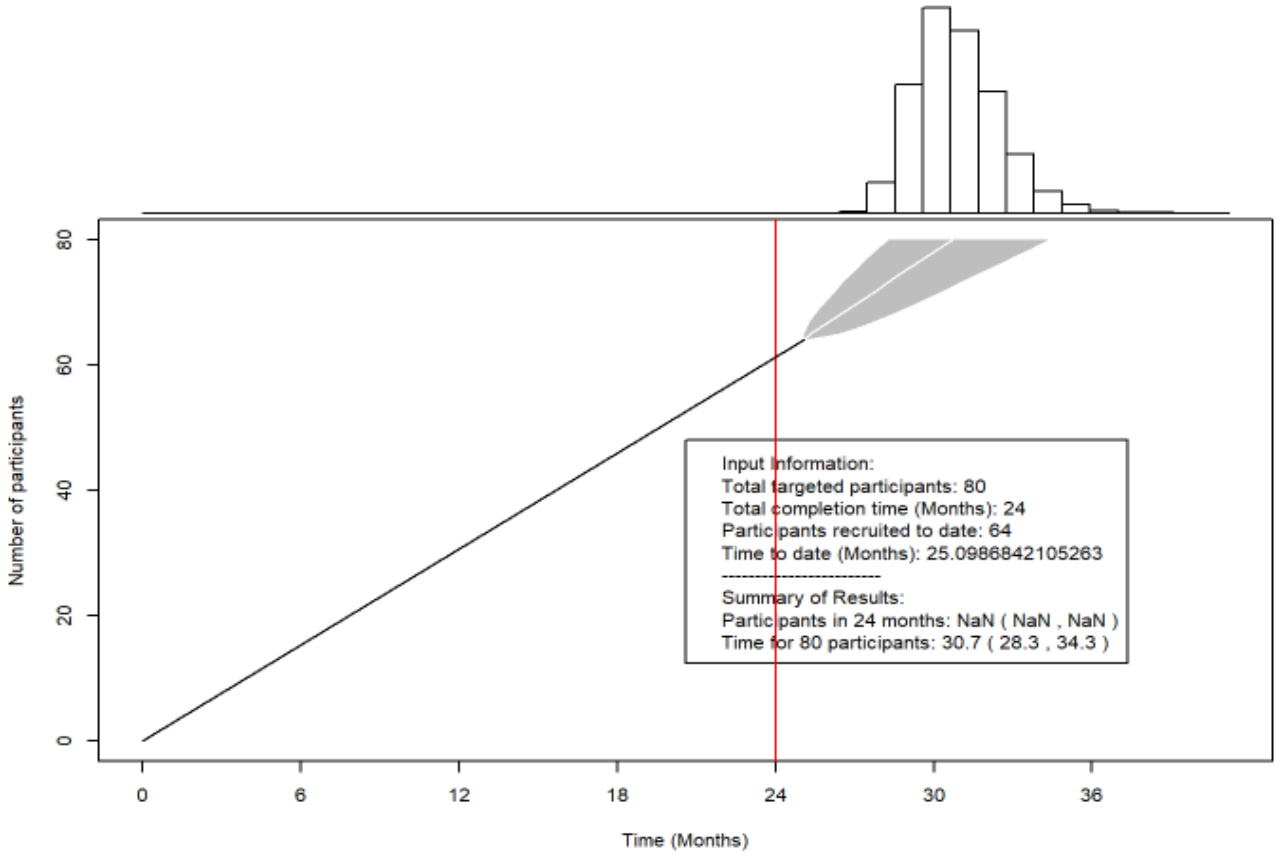
- Accrual Prediction Plots



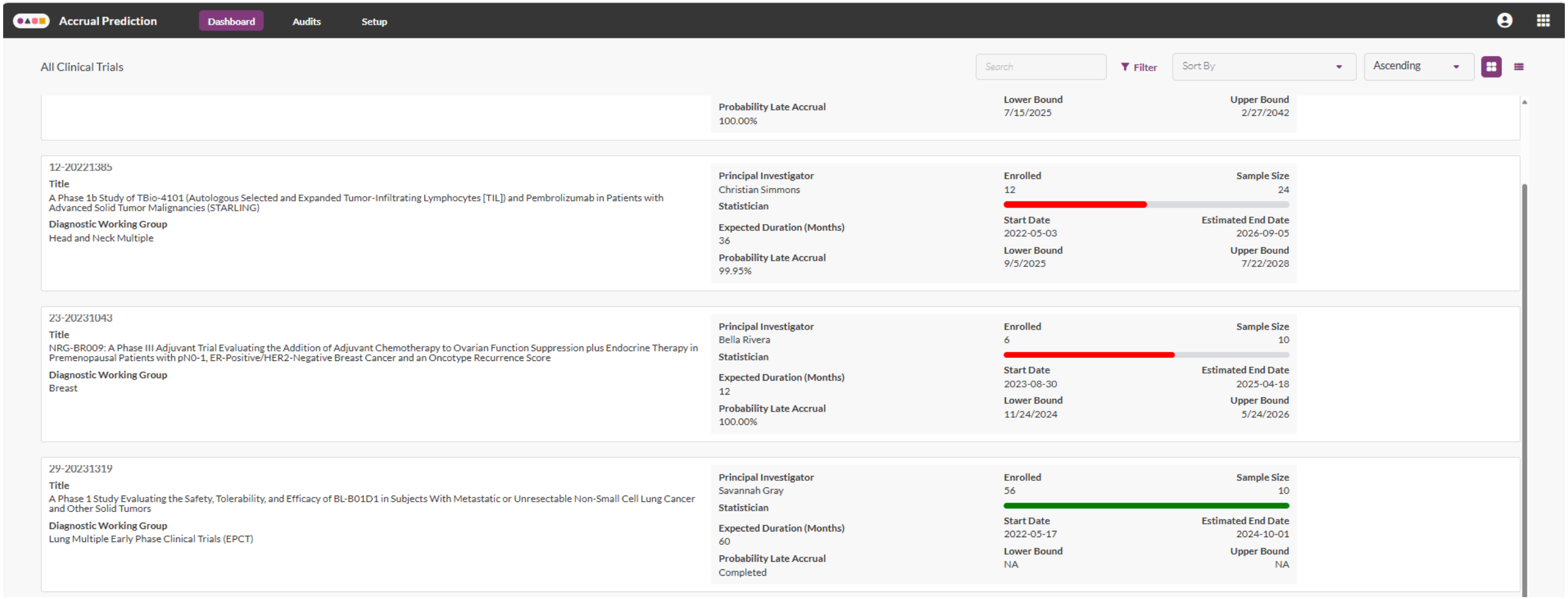


Accrual Prediction: (cont'd)

Here are the prediction plots:

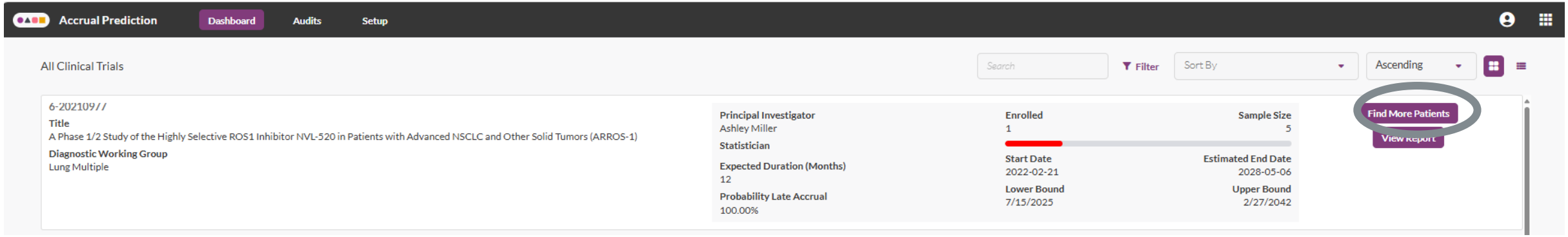


Accrual Prediction: (cont'd)

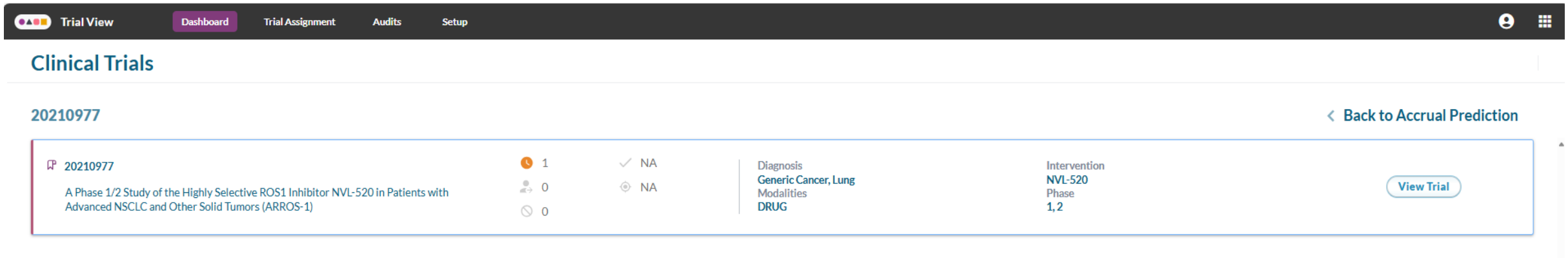


Accrual Prediction: (cont'd)

- Utilize the "Find More Patients" feature to identify additional possible patient matches.



- This will take you into the Trial View module to display any potential pending patients for Review, Send to Admin or Dismissal.



Acknowledgment

- Byron Gajewski, PhD
- Matthew Mayo, PhD, MBA
- Junhao Liu, PhD
- Jo Wick, PhD
- Roy Jensen, MD
- Hope Krebill, MSW, BSN, RN
- Ronald Chen, MD
- OPTIK Team
- KU Clinical Trials Office
  - Tara Lin, MD
  - Natalie Streeter, MSN

Industry Partners: inspirata

- Satish Sanan, CEO
- Laure Tessier-Delivuk, Chief Customer Officer & EVP, Operations
- Inspirata Tech Team.