

Bridging Gaps in Cancer Care Access Across Catchment Areas

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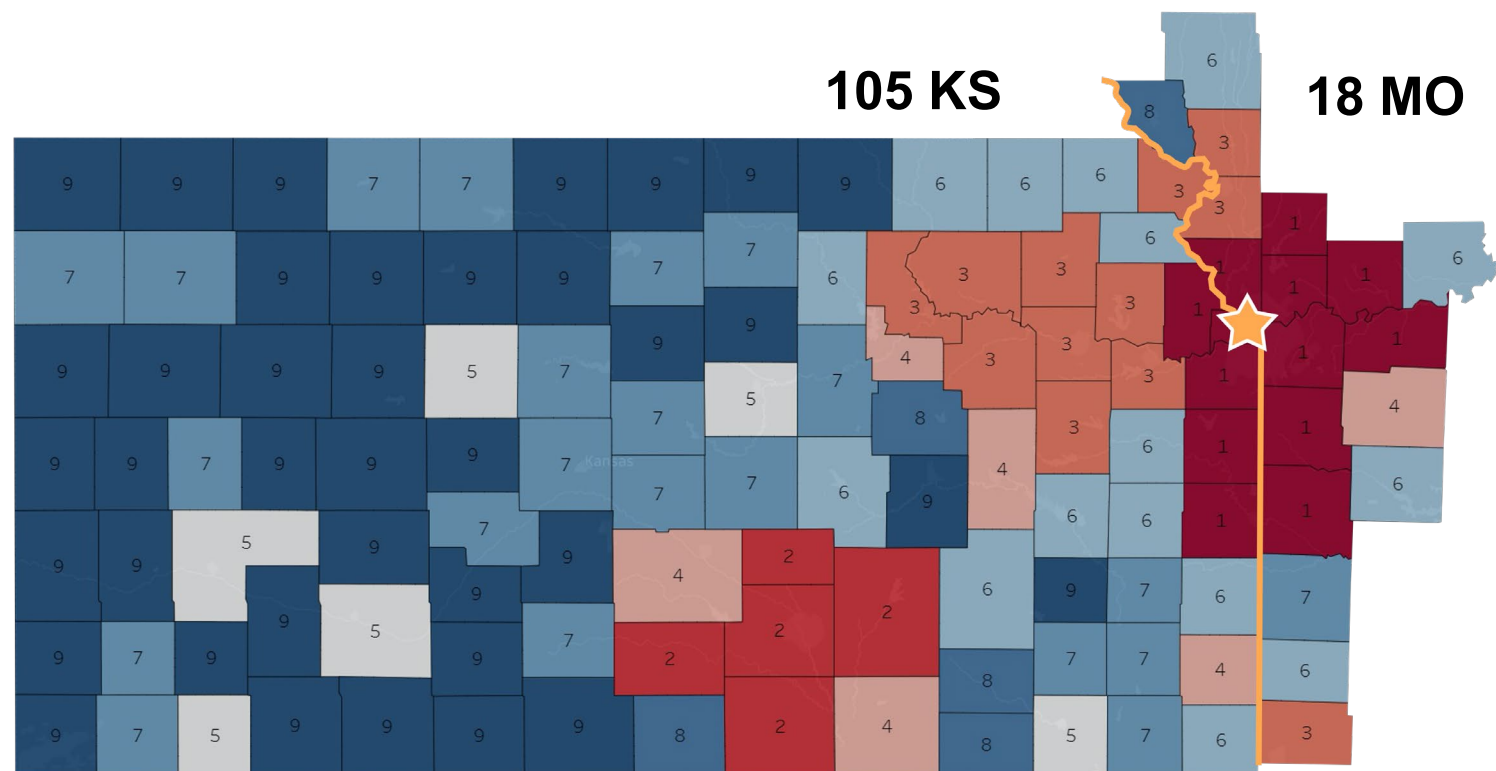
Co-Director, Biostatistics & Informatics Shared Resource

Co-Director, Investigator-Initiated Trials, *The University of Kansas Cancer Center*

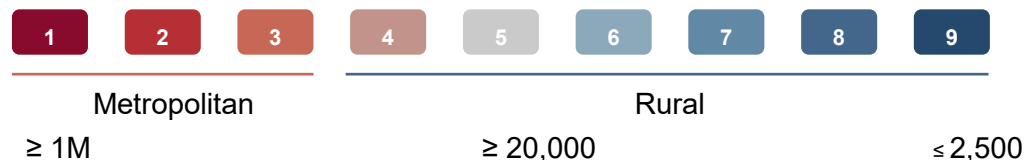
Assistant Director, Neuro Imaging Core, The KU Alzheimer's Disease Research Center

The University of Kansas Cancer Center - COE

- 123 Counties
- 94% of KUCC patients
- 93 Counties Rural
RUCC 4-9 (76%)

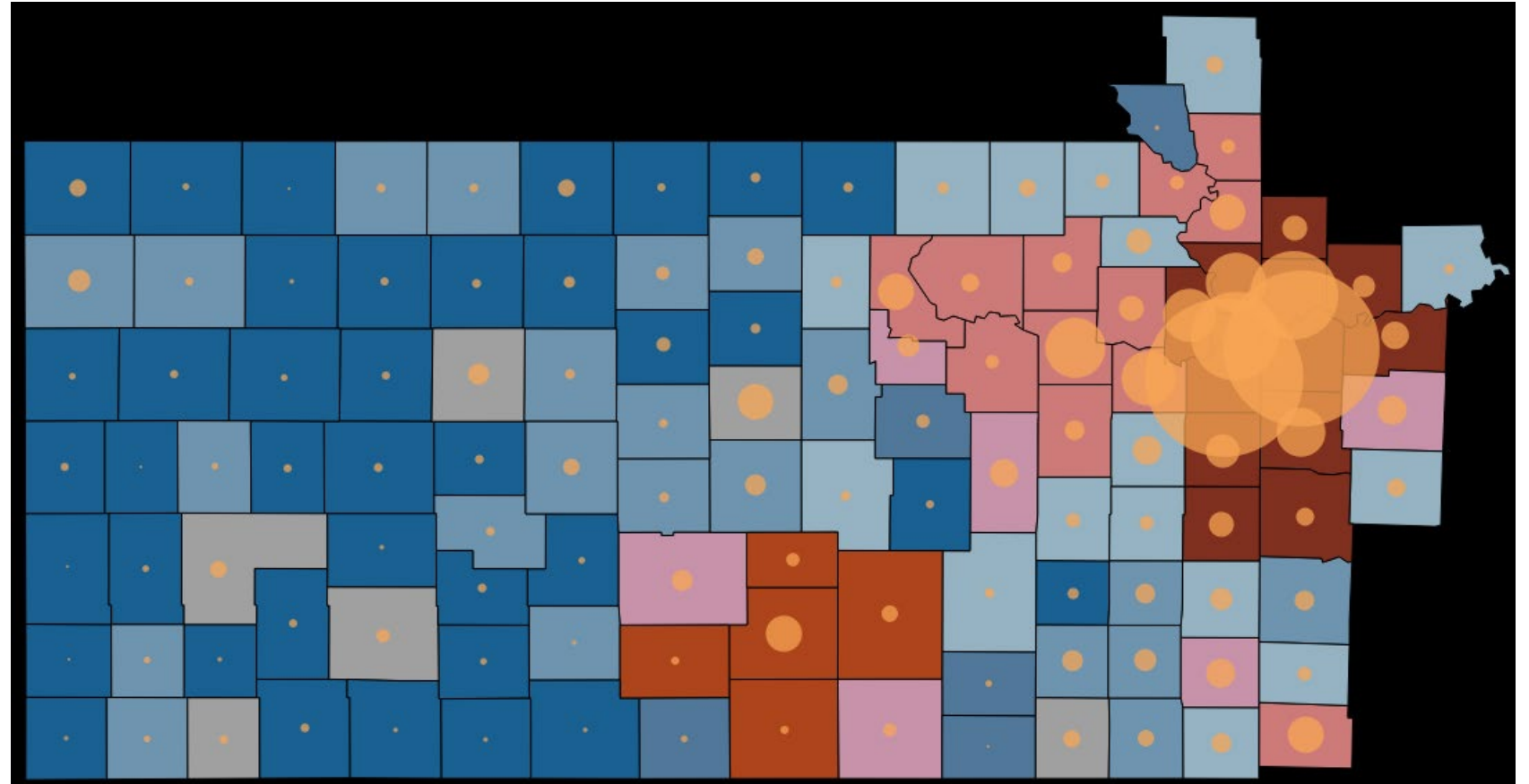


Rural Urban Continuum Code (RUCC 2013)

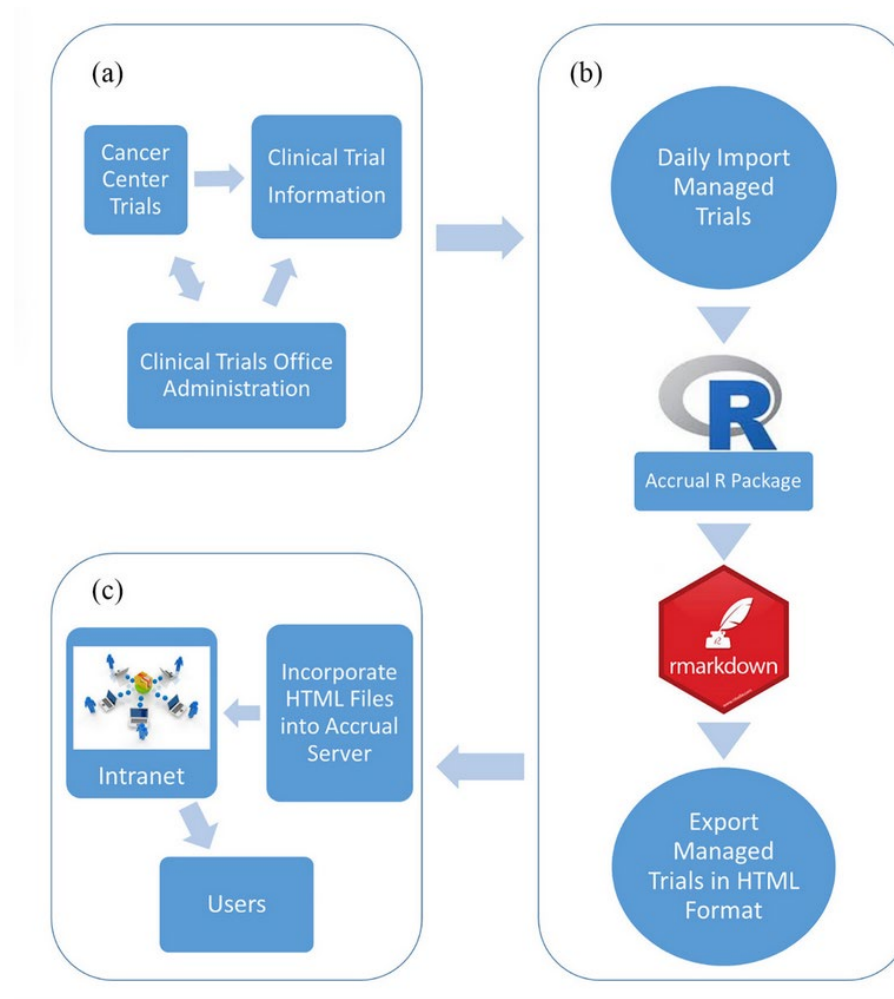


KUCC – Clinical Trial Portfolio

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









Accrual Prediction App



Reference: Liu J, Wick JA, Mudarantakam 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	<ul style="list-style-type: none">• Modify an existing trial or build your own on with a step-by-step process.
Feasibility	<ul style="list-style-type: none">• Population assessment (demographics, disease relevance, eligibility) to run successful trials• Trial criteria manipulation for clinical impacts.
 Accrual Prediction 	<ul style="list-style-type: none">• 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:	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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.
 Trial Performance 	<ul style="list-style-type: none">• 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														
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 pNO-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: 2025-03-21

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 study activation date.

The output show as following:

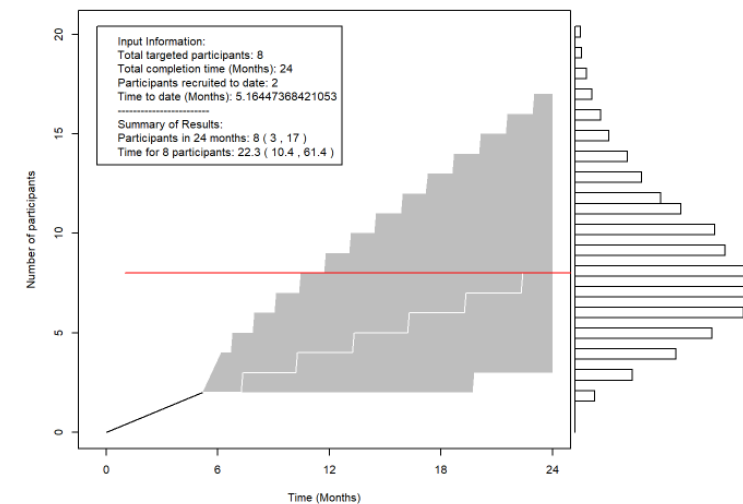
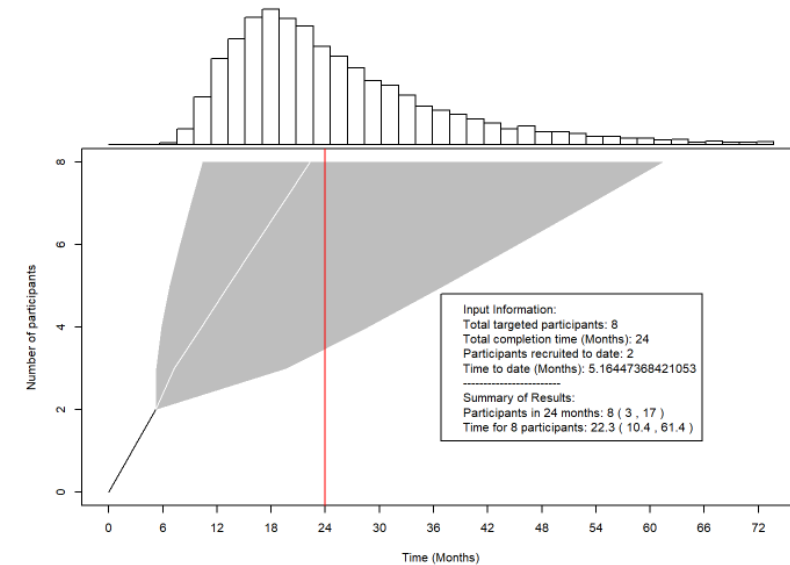
```
## STUDY_TITLE: An Open-label Phase I Study of [redacted] in Participants with Locally Advanced (Unresectable) or Meta-  
static Solid Tumor Malignancies with KRAS G12D Mutation
```

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

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

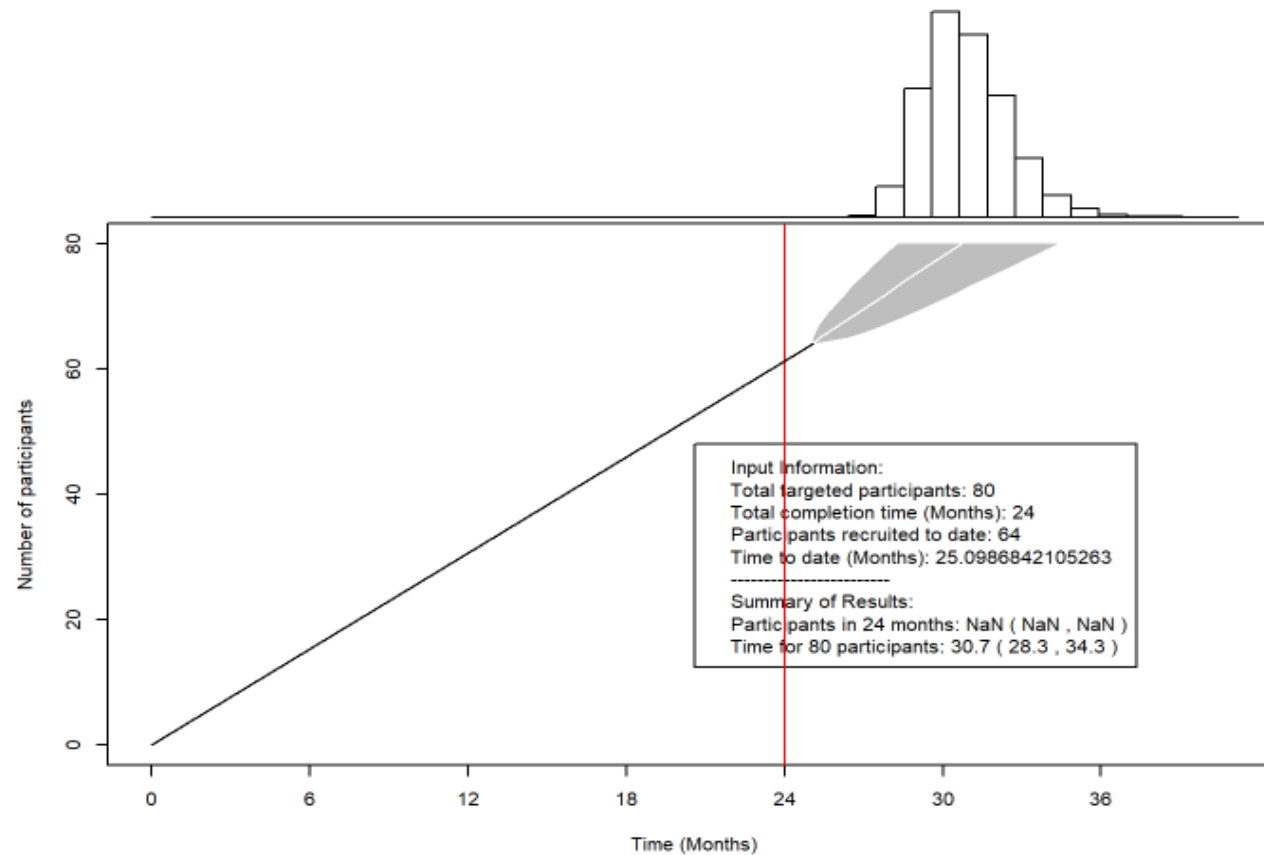
In summary, the predictive completion date is 2026-08-24 with 95% credible interval (2025-08-27, 2029-11-25), based on the study activation date 2024-10-15.

• Accrual Prediction Plots



Accrual Prediction: (cont'd)

Here are the prediction plots:



Accrual Prediction: (cont'd)

All Clinical Trials			
	Search	Filter	Sort By
			Ascending
	Probability Late Accrual	Lower Bound	Upper Bound
	100.00%	7/15/2025	2/27/2042
12-20221385	Principal Investigator	Enrolled	Sample Size
Title	Christian Simmons	12	24
A Phase 1b Study of TBio-4101 (Autologous Selected and Expanded Tumor-Infiltrating Lymphocytes [TIL]) and Pembrolizumab in Patients with Advanced Solid Tumor Malignancies (STARLING)	Statistician		
Diagnostic Working Group	Expected Duration (Months)	Start Date	Estimated End Date
Head and Neck Multiple	36	2022-05-03	2026-09-05
	Probability Late Accrual	Lower Bound	Upper Bound
	99.95%	9/5/2025	7/22/2028
23-20231043	Principal Investigator	Enrolled	Sample Size
Title	Bella Rivera	6	10
NRG-BR009: A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pNO-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score	Statistician		
Diagnostic Working Group	Expected Duration (Months)	Start Date	Estimated End Date
Breast	12	2023-08-30	2025-04-18
	Probability Late Accrual	Lower Bound	Upper Bound
	100.00%	11/24/2024	5/24/2026
29-20231319	Principal Investigator	Enrolled	Sample Size
Title	Savannah Gray	56	10
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	Statistician		
Diagnostic Working Group	Expected Duration (Months)	Start Date	Estimated End Date
Lung Multiple Early Phase Clinical Trials (EPCT)	60	2022-05-17	2024-10-01
	Probability Late Accrual	Lower Bound	Upper Bound
	Completed	NA	NA

Accrual Prediction: (cont'd)

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

The screenshot shows the 'Accrual Prediction' dashboard. The top navigation bar includes 'Accrual Prediction', 'Dashboard', 'Audits', and 'Setup'. The main content area is titled 'All Clinical Trials' and features a search bar, a 'Filter' button, a 'Sort By' dropdown, and an 'Ascending' sort order selector. A table displays trial information for '6-20210977'. The table has columns for Title, Principal Investigator, Enrolled, Sample Size, Start Date, Estimated End Date, Lower Bound, and Upper Bound. The 'Find More Patients' button is circled in red.

Title	Principal Investigator	Enrolled	Sample Size	Start Date	Estimated End Date	Lower Bound	Upper Bound
A Phase 1/2 Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)	Ashley Miller	1	5	2022-02-21	2028-05-06	7/15/2025	2/27/2042

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

The screenshot shows the 'Trial View' dashboard. The top navigation bar includes 'Trial View', 'Dashboard', 'Trial Assignment', 'Audits', and 'Setup'. The main content area is titled 'Clinical Trials' and features a 'Back to Accrual Prediction' link. A table displays trial information for '20210977'. The table has columns for Title, Diagnosis, Intervention, and a 'View Trial' button.

Title	Diagnosis	Intervention
A Phase 1/2 Study of the Highly Selective ROS1 Inhibitor NVL-520 in Patients with Advanced NSCLC and Other Solid Tumors (ARROS-1)	Generic Cancer, Lung Modalities DRUG	NVL-520 Phase 1,2

Acknowledgment

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- KU Clinical Trials Office
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 - Natalie Streeter, MSN

Industry Partners: inspirata

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