



# **Logistics of Alchemist Screening Trial A151216**

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# Presentation Objectives

- To Provide Background and Key Logistics for the Alchemist Screening Trial A151216
- Presenters
  - Chelsea Schultz - Data Manager
  - Shauna Hillman - MS Statistician
    - Supporting Alchemist Screening Trial A151216 and the Erlotinib Treatment Trial A081105

# ALCHEMIST

## (Aduvant Lung Cancer Enrichment Marker Identification and Sequencing Trials)

- 3 Integrated Trials Testing Targeted Therapy in Early Stage Lung Cancer
- Part of NCI's Precision Medicine Effort in Cancer
- Dr. Olwen Hahn will be presenting the scientific portion of the trial on Saturday, Nov 8th at the CRP Education Session scheduled for 9:05 AM
- This presentation will focus on the logistics

# ALCHEMIST Rationale

- ALCHEMIST is studying whether or not treatment based on genotype improves cure rates in early stage (IB-IIIA) NSCLC patients with non-squamous tumors that have been completely resected.

# ALCHEMIST Structure

- **ALCHEMIST is an integrated research effort with 3 component trials:**
  1. **Screening Trial-A151216:** Eligible patients will have their tissue tested for genetic changes in **ALK and EGFR**. If tissue testing is positive, they will be referred to one of the treatment trials. If negative or **not enrolling in a treatment trial** as defined below, they will be followed for 5 years. All patients contribute information to the national public resource for research.
  2. **Erlotinib Treatment Trial-A081105:** Erlotinib vs. placebo will be evaluated in patients with activating **EGFR** mutations (prevalence ~ 10-15%) following standard of care adjuvant therapy
  3. **Crizotinib Treatment Trial-E4512:** Crizotinib vs. placebo will be evaluated in patients harboring the Anaplastic Lymphoma Kinase (**ALK**) fusion protein (prevalence ~5%) following standard of care adjuvant therapy

# ALCHEMIST Design

- ALCHEMIST is designed to accommodate evolving clinical science and research opportunities. Evaluation of other targeted therapies could be added to the research effort as new and promising therapies emerge.

# ALCHEMIST Screening Trial

## Eligibility

- Patient **Pre-Registration** Eligibility Criteria
  - Diagnosis of NSCLC (non-squamous)
  - Pre-Operative: Clinical stage IB ( $\geq 4$  cm) – IIA or Post-operative: pathological stage IB ( $\geq 4$  cm) – IIIA
- Patient **Registration** Eligibility Criteria
  - Complete surgical resection (negative margins)
  - Adequate tissue for EGFR/ALK testing
  - Adequate tissue/blood for NCI CCG genomic research
  - Positive local test of EGFR or ALK alterations allowed

# ALCHEMIST Treatment Trial Eligibility

- To open any of the three trials at your site you must obtain IRB approval for all three trials and must open all three trials at the same time
- Patients [must be registered](#) to the ALCHEMIST SCREENING Trial (A151216) prior to randomization to the treatment trials
- Patients with a tumor positive for translocation or inversion of the ALK gene, [based on local or central testing](#) (eligible for E4512)
- Patients with a tumor positive for activating EGFR mutation, [based on local or central testing](#) (eligible for A081105)
- Must have completed standard of care chemotherapy or chemotherapy + radiation therapy



# ALCHEMIST Registration

- Registration for all three trials will occur through OPEN, go to [www.ctsu.org](http://www.ctsu.org)
- If pre-registering after surgery and a **positive local result** is already available, a pt **may be registered for the treatment trial immediately** after registering the pt for the ALCHEMIST trial
- If a pt is participating in either treatment trial, the pt will have three registrations, pre-registration for A151216, registration for trial A151216, and registration to either A081105 or E4512 which ever is applicable

# ALCHEMIST Specimen Shipment

- Submit to Response Genetics
  - Tissue Specimens for ALK/EGFR analysis
- Submit to NCI CCG Biospecimen Core Resource (BCR)
  - All Scrolls (if applicable)
  - Blood Specimens
  - Recurrence Biopsies
  - Shipments to BCR only occur Monday – Thursday (NO Saturday)
- Include in shipment the Clinical Assay Request form (prints with BioMS shipping manifest)

\*See Section 5.4.1 & 5.4.2 for shipping addresses

## Clinical Assay Request Form (EGFR and ALK)

Patient Initials (First, Middle, Last): \_\_\_\_\_ PATIENT ALCHEMIST (A151216) ID: \_\_\_\_\_

Patient DOB (MM/DD/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_ Surgery Date (MM/DD/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

CRA Ordering Test- RESULTS WILL BE COMMUNICATED TO THIS INDIVIDUAL (please print):

Name (First, Last): \_\_\_\_\_ Institution: \_\_\_\_\_

Order Physician (First, Last): \_\_\_\_\_ CTEP Institution Number: \_\_\_\_\_

Address: \_\_\_\_\_

Street

City

State

Zip

Phone: (\_\_\_\_) \_\_\_\_\_ Fax: (\_\_\_\_) \_\_\_\_\_ Email: \_\_\_\_\_

Submission Date (MM/DD/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_



Check One	Specimen type (enter number of specimens)	Surgical Pathology Case Number	Block Letter
	Formalin fixed, paraffin embedded tumor tissue block (created for study use). (____) 1 H/E stained slide from submitted block (____)		
	Formalin fixed, paraffin embedded tumor tissue block (from clinical pathology department). (____) 1 H/E stained slide from submitted block (____)		
	5, 10 micron tumor tissue sections mounted to charged slides (____) 3, 5 micron tumor tissue sections mounted to charged slides (____) 1 H/E stained slide (____)		

Please ship this request form with BioMS packing slip and the specimen to:

Response Genetics, Inc.  
Pharmaceutical Services  
1640 Marengo Street, 6<sup>th</sup> Floor  
Los Angeles, California 90033

# ALCHEMIST Follow-up

- Those not enrolled on A081105 or E4512 are followed for 5 years every 6 months see section 7.3
  - Minimum Follow-up data collected - focused on subsequent therapy and recurrence
- Those enrolled on A081105 or E4512 will be followed via the respective protocol and study calendar
- A report summarizing the EGFR and ALK results will be sent directly to the sites from Response Genetics
  - Report will be sent within 14 **business** days of submission

# ALCHEMIST Data Collection

- Data entry for all three trials will occur via Medidata Rave
- CRP and site investigators will receive a Rave invitation once their site has IRB approval for all three trials
- A short eLearning will be required prior to access (only required if first time Alliance user of Rave)
- At the time of Pre-registration
  - Complete Screening and CRA Contact Form
- At the time of Registration
  - all other on-study forms (including epidemiology data collection) will roll out for completion in the baseline folder
- Follow-up folders will roll out based on the site indicator of registration to either A081105 and E4512 and BCR assessment of sample quality. An indicator will be derived from these fields displaying whether follow-up will be expected for this trial

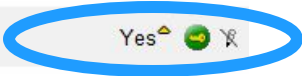
# ALCHEMIST Data Collection

- Information about how patients will be followed will be derived on the Patient Status Form found in the Baseline and Survival Folders
- Baseline Folder

🏠 A151216 🧪 Stage II Testing Round 13 👤 SLH003 📁 Baseline 📄 Patient Status: Baseline

Subject: SLH003  
Page: Patient Status: Baseline - Baseline

Cycle	0	👍	✅	🗑️
Is the patient enrolled in a targeted therapy trial from the following list?	None	👍	✅	🗑️
RG (Response Genetics) indicator of tissue adequacy for EGFR genotyping <i>(derived field)</i> ?	Adequate	👍	🟢	🗑️
BCR (Biospecimen Core Resource) indicator of tissue and blood adequacy for research genomics <i>(derived field)</i> ?	Adequate	👍	🟢	🗑️
Will the patient be followed on ALCHEMIST (A151216) trial? <i>(derived field)</i> ?	Yes	👍	🟢	🗑️
Comments		👍	✅	🗑️





# ALCHEMIST Data Collection

- Survival and Disease Status Follow-up Folder


## Adjuvant targeted therapy

Is the patient enrolled in a targeted therapy trial from the following list?

None  


## SMOKING STATUS

### Baseline indicator of smoking status *(derived)*

Has the patient smoked 100 cigarettes (five packs) in their lifetime? *(derived field)* 

Yes   

### Previous Visit Smoking Status *(derived)*

Has the patient reported quitting smoking on a previous visit? *(derived field)* 

No   

### Current smoking status

**INSTRUCTIONS:** If the patient was smoking at baseline and has never reported quitting smoking previously, complete the following question

Has the patient **completely** quit smoking cigarettes since the last reported smoking status?

*(If yes), how long has it been since the patient completely quit smoking cigarettes?*

*(If yes), number of days/weeks/months/years (1 – 99)*

Will the patient continue to be followed on ALCHEMIST (A151216) trial? *(derived field)* 

Yes   

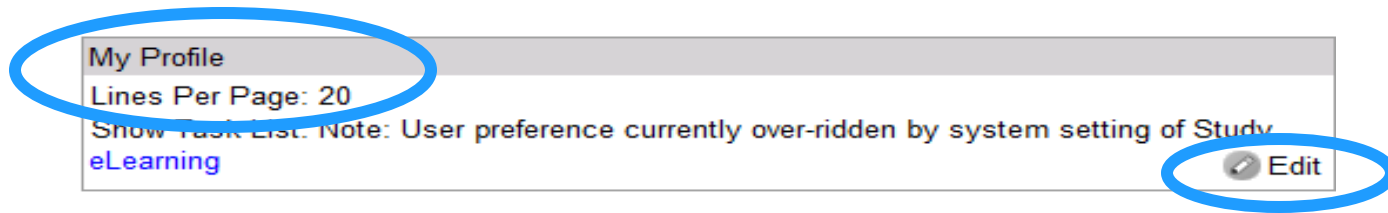
# ALCHEMIST Data Collection

- Pagination may be required on a few of the on-study forms depending on your Rave Set-up parameters (this is not unique to this trial)
- If enrolled on A081105 or E4512, and the patient has a recurrence, go to the A151216 Screening Trial in Rave and the add event section on the subject home page and add the Specimen Submission: Recurrence Tissue form to indicate whether you did or did not submit a sample
- The Specimen Submission: Recurrence Tissue Form will automatically be rolled out if the patient is being followed via the ALCHEMIST screening trial and a recurrence is indicated



# ALCHEMIST Data Collection

- You may update your EDC settings by going to “My Profile” and the “edit” icon. Update the number of lines displaying from 20 to 200 so all lines of the log line table display at once



# ALCHEMIST Data Collection

- If your lines per page is left at the default of 20 you will need to select “2” or “3” below to get to the second and third page of occupational exposures

OCCUPATION REVIEW CHECKLIST

Did the patient ever have a job as any of the following? (Respond below)

INSTRUCTIONS: Depending on your settings in Rave, this table may be paginated. If the options are available, click on Paginate and select Show All Lines or click on the numeric page numbers at the bottom right corner of the table. If these options are not available, you are already viewing the entire table.

#	Occupation/Job	Job held	Number of years job held	
1	Miner	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Truck driver	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Bus driver	Yes	2 years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Taxi driver	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Heavy equipment operator	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Construction-related occupation	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Vehicle mechanic	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	Machinery mechanic	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Dock or warehouse worker	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Ship building or ship repair	No	years	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Paginate 1 2 3

# ALCHEMIST Data Collection

- To find the Add Event section navigate to the Rave Subject Home Page and select the Specimen Submission Recurrence Tissue Form and the Add button

The screenshot shows the Rave Subject Home Page interface. At the top, there is a navigation bar with a home icon, the subject ID 'A151216', the study name 'Stage II Testing Round 13', and the user ID 'SLH001'. Below the navigation bar, there is a 'Subject Enrollment' section with a green checkmark icon. A table displays the subject's visit history:

Visit	Date
Baseline	30 Jun 2010

Below the table, there is an 'Add Event' section with a dropdown menu. The dropdown menu is open, showing several options: 'Consent Withdrawal', 'Internal Use Only: MCCC Deviation', 'Lost to Follow-Up', and 'Specimen Submission: Recurrence Tissue'. The 'Specimen Submission: Recurrence Tissue' option is highlighted with a blue oval. To the right of the dropdown menu is an 'Add' button, which is also highlighted with a blue oval. Below the 'Add Event' section, there is a 'Reports' section with a list of reports: 'Query Detail - Query Detail Report' and 'Subject PDF Report - Subject PDF Report'.

Icon Key

# Take Home Message

- To open the trial you must obtain IRB approval for all three trials (A151216, A081105, E4512)
- Either 2 or 3 registrations will occur for participation in this trial
- All patients will be followed regardless of EGFR and ALK status with the exception of those with inadequate samples for genomic testing
- Required protocol samples will be logged in Bioms and sent to either Response Genetics or the BCR
- Data entry will occur in Medidata Rave
- Navigation for this trial will be driven based on the site entered information on participation on trial A081105 and E4512 and the BCR derived sample quality parameters. Follow-up status will be derived and displayed within Rave
- If any questions about data collection please contact Chelsea Schultz at 507-266-6247

# Questions