

# Introduction to FDAAA

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## What is FDAAA

- Food and Drug Administration (FDA) Amendments Act, Section 801
- Established in 2007
- Requires registration and reporting of information on applicable clinical trials (ACTs) on CT.gov
  - Controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act
- 2016 regulations:
  - 42 Part 11 - *Final Rule for Clinical Trials Regulation and Results Information Submission*
  - Increase availability of information about clinical trials and clarify FDAAA 801

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## NIH Policy

- Effective January 18, 2017
- **ALL** CTs funded by NIH will register and report trial results in Clinicaltrials.gov
- NIH CT definition:
  - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
  - Interventions include:
    - drugs/small molecules/compounds, biologics, devices
    - procedures (e.g., surgical techniques)
    - delivery systems (e.g., telemedicine, face-to-face interviews)
    - strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits)
    - treatment strategies
    - prevention strategies
    - diagnostic strategies

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## Why do we report?

- It's the law
- Inform clinicians and the public about clinical trial results
  - Transparency
    - Report positive and negative trials
  - Reduce redundancy

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## Role of OPS in Complying with FDAAA & NIH Policy

- Serve as the Intramural Liaison for Clinicaltrials.gov
- Serve as Administrator for Protocol Registration System (PRS)
  - Register Protocols
    - Send CT.gov summary to PI for review and approval
  - Serve as the “Responsible Party”
    - When it is time to report results, switch RP to PI and send ct.gov log-in information
- Monitor for Compliance

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## Protocols Posted by NIHCC

[Find Studies](#) [About Studies](#) [Submit Studies](#) [Resources](#) [About Site](#)

[Home](#) > [Search Results](#) > Study Record Detail

Trial record 1 of 1 for: 15-C-0145

[Previous Study](#) | [Return to List](#) | [Next Study](#)

**Phase I/II Study of the Anti-Programmed Death Ligand-1 Antibody MEDI4736 in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers**

This study is currently recruiting participants.

See [Contacts and Locations](#)

Verified May 19, 2017 by National Institutes of Health Clinical Center (CC) ( National Cancer Institute (NCI) )

Sponsor:  
National Cancer Institute (NCI)

Information provided by (Responsible Party):  
National Institutes of Health Clinical Center (CC) ( National Cancer Institute (NCI) )

ClinicalTrials.gov Identifier:  
NCT02484404

First received: June 25, 2015

Last updated: July 12, 2017

Last verified: May 19, 2017

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

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# Cancer Vaccine Targeting Brachyury Protein in Tumors

Sponsor:

National Cancer Institute (NCI)

**Information provided by (Responsible Party):**

James Gulley, M.D., National Cancer Institute (NCI)

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## Updating Protocol Information

- Nightly feed from Protrak
  - Continuing review/Amendments
  - Request of research team
    - [CC\\_Protocol\\_Services@cc.nih.gov](mailto:CC_Protocol_Services@cc.nih.gov)

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## When do we report results data?

- Initial results must be reported within 1 year of the primary completion date
  - Date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome
- Once the clinical study has reached the study completion date, update the Study Completion Date to reflect the actual study completion date
  - Date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events
- Results reporting begins ~3 months before it is due.
  - Holidays and leave are taken into consideration so may be > 3 months

## What do we report?

- Administrative data
- Baseline Characteristics
- Participant Flow
- Outcome Measures
- Statistical Analysis
- Adverse Events
- Upload protocol and consent (last version)
  - Ensure tech transfer agreement allows this
  - CCR will not redact

## What is the Role of the PI?

- Ensure study data is setup properly in C3D
- Know location of data
- Routinely QA data
- Designate a FDAAA POC
- Provide, review and/or edit results data
  - Identify the primary and secondary outcome measure data/format
- Approve and Release record in the CT.gov database
- Before departing the NCI, report results data (if applicable)

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## What documents will the PI be asked for?

- Publications/manuscripts
- Abstracts
- Oral presentations
- Excel spreadsheets
- Other data
- Lisa requests of ASRC Federal a FDAAA report from J-review
  - Participant flow data
    - Demographic
    - Reason off study
  - Baseline characteristics
  - AE

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## What happens after we report the data?

- CT.gov QA Review
  - 30 days
  - CT.gov may review publications and protocol information against data reported
- QA Review Comments returned
  - Major
  - Advisory
- Record updated on CT.gov – this then makes the data available to the public

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## Posting results

- Applies to ACT
  - Study start date on or after Jan. 18, 2017
  - First submitted results information beginning in January 2020
- RP will be notified via email that QC review comments are available for review and action
- NLM will publicly post submitted results
  - Within 30 days of submission
  - Regardless of whether quality control (QC) review has been completed
    - Also, Major comments about relevant sections
      - Note about the QC process

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## Potential Penalties

- >10K a day (civil action)
- Criminal action
- Suspend privileges/Withhold grant funds

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## The Internet and Social Media

- [FDAAA Trials Tracker](#)
  - Oxford University team tracks compliance with FDAAA results reporting (e.g., overdue, reported late) and posts to their website
- Twitter
  - Delinquent data from the FDAAA Trials Tracker can be tweeted and shared with the public

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## Example

12-C-0056

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## CCR Process

- Role of the Database Administrator
  - NCI CCR liaison for clinical trials results reporting
- Role of the PI, statistician, research nurse staff
  - Provide data, answer questions & QA Review Comments from CT.gov
- Role of the data management staff
  - Provide FDAAA reports

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## When does the process start?

- Results reporting begins ~3-4 months before it is due.
- Holidays and leave are taken into consideration so may be > 3 months

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## What is requested from the PI and research team?

- Confirm the PCD and/or SCD
- Provide publications, abstracts oral presentations, Excel sheets, and other data
- Primary and secondary outcome measure data/format

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## What is requested from data management?

FDAAA reports

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## Reminders

- Results reporting begins ~3 months before it is due
  - Holidays and leave are taken into consideration so may be >3 months
- Keep track of your primary completion date and study completion date and update them accordingly
  - Location of data
  - Routinely QA data
  - Designate a FDAAA POC
- Review the primary and secondary endpoints in the protocol

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## Resources

- ClinicalTrials.gov <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>
- Results Templates and Examples  
[https://prsinfo.clinicaltrials.gov/results\\_table\\_layout/ResultSimpleForms.html](https://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html)
- NIH Sourcebook  
<https://oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing/guide-fdaaa-reporting-research-results>
- Trial Reporting in ClinicalTrials.gov-The Final Rule  
<http://www.nejm.org/doi/full/10.1056/NEJMSr1611785#t=article>

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## Resources

- FDAAA Trials Tracker  
[fdaaa.trialstracker.net/](https://fdaaa.trialstracker.net/)
- Civil Money Penalties Relating to CT.gov Databank  
<https://www.fda.gov/media/113361/download>
- Seife et al. v. HHS et al.  
[https://clinicaltrials.gov/ct2/manage-recs/faq#fr\\_41](https://clinicaltrials.gov/ct2/manage-recs/faq#fr_41)

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## Contact Information

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# Thank you!

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