Clinical Trials Registration and Reporting Requirements, Policy Table

When does information need to be submitted to or posted on ClinicalTrials.gov?

Recommended Registration Timelines for Clinical Research Operations

For all studies where MD Anderson is the responsible party for reporting, the enclosed timelines are to be followed. The Clinical Research Study Registration Team (CR Reg), Office of Protocol Research Review & Reporting will follow the following schedule for Registration, and Results Reporting.

	Institutional Timeline	**NIH FDAAA Timeline**
Registration:	Registration done prior to first subject enrollment on study. The CR Study Registration Team (CR REG) completes submission after IRB approval (before first subject is enrolled). This includes data included in the registration template from clinicaltrials.org, a redacted copy of the protocol, and a Statistical Analysis Plan if one is not included in the protocol. Updates are made to registration records within 7 days of IRB approved changes. Corrections are made within 15 days of notice. Records verified every 6 months for anticipated primary completion dates.	Registration submission no later than 21 days after enrollment of the first trial participant. Public posting generally occurs within 30 days after submission. Updates to study information or status required within 30 days of approved changes. Corrections to submitted information required within 15 days for registration information. Record verification required once a year.
Results information Reporting:	Results posted on public site within 12 months of actual primary completion date for primary outcome(s): - PI provides results data elements (templates) within 6 months of results due date to allow for CR REG entry to results tables. - CR REG completes draft results within 4 months of results due date, PI approves drafted results within 15 days of receiving. - Submission occurs within 3 months of results due date. - Corrections and response to inquiries returned within 15 days to CR REG, and submitted within 25 days.	Standard submission deadline within 12 months after the first date of final data collection for the pre-specified primary outcome measures (primary completion date) and posting within 30 days after submission. Corrections to submitted information required within 25 days for results information.

Posting of Final Informed Consent Form after Study Closure	When study is moved to Closed to New Patient Entry, the CR-Registration Team will send an email to study team members to identify the following: - Is closure permanent? - If yes, ascertain the last patient study visit and within 60 days of that, upload the final version of the Informed Consent to Clinicaltrials.gov - If no, alert the study team that if the Closure becomes permanent to Notify the CR Reg team so the final version of the ICF can be submitted to clinicaltrials.gov	After study closure, posting due 60 days after last patient visit.

Maintenance of Registration Record:

Just for reference, not to be included in the POLICY tables.

Data Element	Deadline for Updating (i.e., not later than the specified date)
Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
Intervention Name(s)	30 calendar days after a nonproprietary name is established.
Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after an NCT number is assigned to a newly created expanded access record. [1]
Expanded Access Status	30 calendar days after a change in the availability of expanded access.
Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
Overall Recruitment Status	30 calendar days after a change in overall recruitment status. [2]
Individual Site Status	30 calendar days after a change in status of any individual site.
Human Subjects Protection Review Board Status	30 calendar days after a change in status.
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
Enrollment	At the time the primary completion date is changed to "actual," the actual number of participants enrolled must be submitted.
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
Responsible Party, by Official Title	30 calendar days after a change in the responsible party or the official title of the responsible party.
Responsible Party Contact Information	30 calendar days after a change in the responsible party or the contact information for the responsible party.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Record Verification Date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

Notes:
1. If expanded access to an investigational drug product becomes available after a clinical trial of that drug product has been registered and an expanded access record has not yet been created, a responsible party who is both the manufacturer of the investigational product and the sponsor of the applicable clinical trial must also, not later than 30 calendar days after expanded access becomes available, submit the data elements in accordance with §11.28(c) to create an expanded access record.

2. If Overall Recruitment Status is changed to "suspended," "terminated," or "withdrawn," the Why Study Stopped data element must be submitted at the time the update is made.

Source: https://clinicaltrials.gov 16 September 2016

Clinical Research Ops Registration and Results for ClinicalTrials.gov: Details and Instructions

	Central Process	Related Details
Registration:	Registration done prior to first subject enrollment on study for applicable clinical trials (ACT) where MD Anderson responsible party. The CR Study Registration Team (CR REG) completes submission after IRB approval (before first subject is enrolled), unless study registration is provided by study sponsor or other organization with oversight.	PI can find applicable clinical trial decision and status of ClinicalTrials.gov registration in related ClinicalTrials.gov field on CORe Protocol Page, and PDOL Web Display. CR REG updates for all clinical trials (standard protocols and protocol applications) submitted within PDOL. NCT field = *NCT #*, *Not Registered*, or *Not Applicable*. Not registered implies ACT but not registered by responsible party yet. Emails confirming other sponsor registration or NIH funding routinely sent to PI. ICMJE decision solely based on PI notification.
Who is subject to the requirements?	Responsible party is considered to be the study sponsor (i.e. IND or IDE holder) or the initiator of the study, considered the grantee organization for NIH-funded trials) or a sponsor designated PI who is responsible for conducting the study, and has access to and control over the clinical data to analyze the data and publish the results	MD Anderson is considered "Study Sponsor" for institutional studies registered centrally; however, PI is ultimately responsible for compliance to ClinicalTrials.gov, accuracy of registration record, results submission and posting. PI must confirm outside registration (e.g. Industry or National study) of ACTs, and provide NCT to CR REG prior to study activation.
Which clinical trials are subject to requirements?	Clinical Research and Clinical Trials defined by the NIH and NCI include interventional IND or IDE study FDA-regulated drug or biologic product with at least one US location, manufactured in and exported from US, other than Phase 1. Registration is optional for observational studies, population based studies, or other non-ACTs that are not NIH funded, CMS qualified or subject to ICMJE policy.	Interventional clinical trials submitted under standard protocol with NIH funding that meet the NIH clinical research or clinical trial definition <link to definition>. FDAAA ACT is subset of NIH definition of clinical research trials <link to definition>.

When does info get submitted?	With IRB approval of a PDOL submitted protocol the CR REG team reviews for ACT status then registration accomplished. Registration or non-applicability is documented in CORe and PDOL where the clinical trials identifier (NCT#) is added for a registered study. Updates for study amendments or status changes are accomplished within 15 days of the IRB approval using the PDOL and CORE documentation. Registration records may be updated or modified at any time, corrections returned within 15 days. Minimally records are updated every 6 months for ACT review with record verification at least once a year.	Registration records for institutional studies are routinely created with IRB approval, IND or IDE approvals are needed prior to submission and multi-site information, location and status may be needed to complete the record. Typically first submissions of standard protocols receive an identifier (NCT) with 3-5 business days. Displays on ClinicalTrials.gov may lag several days behind an update acceptance.
How PI is notified.	CR REG sends PI and research team identified in PDOL additional contacts copy of registration record for review and confirmation of outcomes as listed.	With original study registration, layouts of arms, interventions and outcomes should be reviewed for correctness and consistency. ClincialTrials.gov QA questions may arise with a submission and are forwarded to PI. PI must respond to requests for corrections within 15 days. If outcomes are modified in updates an email is sent to PI for validation.
What info is used for Registration?	Descriptive info about the trial (brief title, study design, eligibility criteria, outcome measures and recruitment details) reproduced from approved PDOL protocol documents. If lead site for multi-center study additional information on site status, site investigator and location details will need	Following IRB approval and study registration, PI receives email with registration receipt to confirm information entered. PI must provide regular updates for anticipated PCD.

	to be supplied to CR REG team with any changes, at minimum every 6 months.	PI may need to forward sponsor registration of industry studies with NCT to CR REG prior to study activation.
	Central Process	Related Details
Results: 1. Which have results 2. How do we ID them 3. How do we notify staff of due date 4. How do we get info 5. How do we enter info 6. How do we review/QA 7. How do we submit 8. How Q&A answered 9. How confirm compliance to prep/entry/deadline/posting	Results posted on public site within 9 months of actual primary completion date, posting within 30 days after submission approval. The CR Study Registration Team enters and submits PI provided data in required results tables three months before results due date. Data for results tables must be provided to team in needed format four months before due date to ensure time for questions and modifications to record before submission.	Phase I studies and voluntarily registered studies are not subject to the results requirement. Results due dates are calculated from PCD for primary outcomes. *Primary completion date (PCD)* is defined as date at which final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol was terminated. PCDs are verified via email minimally once every six months.
Which clinical trials are subject to Results requirements?	ACTs, Interventional clinical trials other than Phase I, and those with health related outcomes as defined by NIH.	ACT defined by FDAAA, expanded by NIH Clinical Trial definition.
When does Results info get submitted?	Results posted on public site within 12 months of actual primary completion date for primary outcome(s): - PI provides results data elements (templates) within 6 months of results due date to allow for CR REG entry to results tables. - CR REG completes draft results within 4 months of results due date, PI approves drafted results within 15 days of receiving. - Submission occurs within 3 months of results due date.	Data collection for results entry and drafting of results tables accomplished following actual PCD (date at which last patient treated or data point collection occurs for primary outcomes). CR REG enters provided data into results tables upon receipt. Draft returned to PI for review and approval within 15 days. Submission to occur 3 months prior to results due date.

	- Corrections and response to inquiries returned within 15 days to CR REG, and submitted within 25 days.	

How PI is notified of Results requirements & due date.	At actual primary completion date, CR REG sends PI notice of one year timeline and templates for completing a standard results submission. PI is asked to designate a results contact, if not themselves, to work with CR REG to complete results entry. At 9 months prior to results due date, CR REG sends reminder results deadline requires submission of results minimally 3 months prior to deadline to ensure public posting requirement satisfied. CR REG prepares a draft results record and provides it to PI and research team. At 6 months prior to results due date, CR REG sends reminder and requests completed templates be returned for entry into the draft results tables. At 3 months prior to results due date, CR REG sends another reminder and contacts the PI specifically. At 1 month prior to results due date, PI notified results considered late per FDAAA posting requirement and study information added to ClinicalTrials.gov Results planning report provided to VP Clinical Research office.	Prospective notification by CR REG for needed results reporting using actual PCD. Notices outline four results modules and requirements. Results documentation to be supplied to CR REG team for drafting and submission of results. PI Notice of late results posting one prior to results due date, and non-compliance message posted with results on ClinicalTrials.gov site. ClinicalTrials.gov Results planning reports provided to institutional management for follow up.
What info is used for Results?	Scientific study information is submitted as four separate modules: • Participant Flow • Demographic and Baseline Characteristics (Age, Gender and Region of Enrollment) • Primary and Secondary Outcome Measures and Statistical Analysis • Adverse Event Information: Serious Adverse Events and All Others where tables separated by AE term for arm/cohort with number of participants and events for each	Results entry is tabular format; templates are provided with results notification.
