RED
Research Education Development

Symposium for Research Administrators

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Clinical Trials are Unique

What You Need to Know

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Agenda

- What is a clinical trial?
- Investigator-Initiated Trials
- IRB Review
- Financial Issues
- Campus Resources
- Questions

What is a clinical trial?

- A research study that prospectively assigns human participants … to one or more health-related interventions to evaluate the effects on health outcomes[1].
- Usually one of the final stages, after lab research and animal studies.
- Phases
- Offers access to treatments that would not be available otherwise
- Clinical trials are required for FDA approval of a drug/device

1) http://www.who.int/topics/clinical_trials/en/

Oversight of Clinical Trials

- In the US- Dept. of Health & Human Services (HHS)
  - Includes NIH, FDA, OHRP (Office of Human Research Protections)
  - 21 CFR (FDA), 46 CFR (OHRP)
- Additional Guidance
  - Nuremburg Code, Declaration of Helsinki, Belmont Report
- ICH/GCP
- These regulations and guidance documents establish subject rights and minimum standards for clinical research
  - IRB review, consenting, privacy protections, reporting requirements, etc.

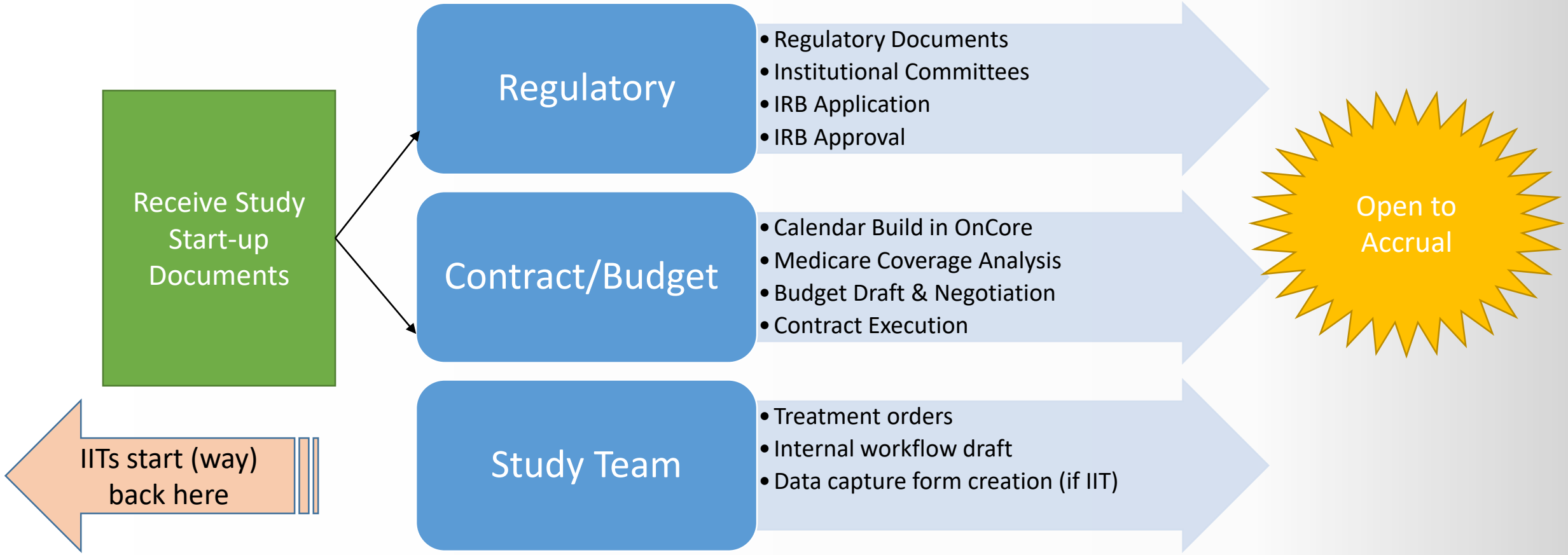
Sponsors & Funding

- Sponsor- FDA defines as the person/entity that initiates a clinical investigation
  - Sponsor-Investigator: sponsors and conducts the trial (IITs)
  - Important note: sponsors have additional responsibilities
- Contract Research Organization (CRO)
  - Sponsors often outsource the day-to-day work of running studies
  - Positives and negatives
- Funding
  - Can be a variety of sources- federal, other non-profit, industry, institutional
  - Can be a combination of sources

Investigator Initiated Trials (IITs)

- Studies written by UW investigators
- Much more involved than an external study
  - PI may end up being a sponsor-investigator → more responsibility
  - PI may hold the IND/IDE with the FDA
  - All study documents will be drafted internally
- Can be submitted for funding
  - Grants- federal, other non-profit
  - Industry- can be for drug supply only or for financial support as well
- Best supported by an experienced team, but campus resources exist to help you.

Clinical Trials



Institutional Review Board (IRB)

- The IRB is responsible for ensuring the protection of human subjects
  - Initial review, continuing review, and review of changes/amendments
- HS-IRB (Health Sciences)- reviews IITs, federal studies, others
  - Electronic application via ARROW
  - **Delays can occur if protocol or applications are poorly written**
- WIRB- UW has an agreement with Western IRB to have WIRB review certain industry studies
  - HS-IRB WIRB Liaison must do a pre-review to ensure the study qualifies for WIRB review and that local/institutional language is in the consent form; also review HIPAA

Clinical Trials Budgets

- A good budget ensures that you know what the study will actually cost, which increases the odds that it will be completed!
- A clinical trial budget should include costs for all of the following:
  - Staff/research effort
  - Clinical procedures (if applicable)
  - Shared Services budgets
  - Administrative costs for research group (start-up/maintenance fees, IRB submission prep, monitoring fees, etc.)
  - Indirect- based on the sponsor and funding source (federal studies are calculated on MTDC)
- Rates will vary based on sponsor type and funding source

Ancillary Services & Compliance Review

- ASR
  - All studies with UWHC/UWMF procedures go through ASR- includes review by lab, radiology, etc., and also a compliance review, which helps ensure that we are billing per Medicare rules
- Coverage Analysis
  - “Qualifying” clinical trials are eligible to have certain clinical costs billed to a subject’s insurance
  - The process of determining if a trial is “qualifying”, and which items can be billed, is called a Medicare Coverage Analysis (MCA)
  - CMS regulations- NCD 310.1
  - Informs budget to ensure we don’t request sponsor payment for something that will also go to insurance/subject (double-billing)

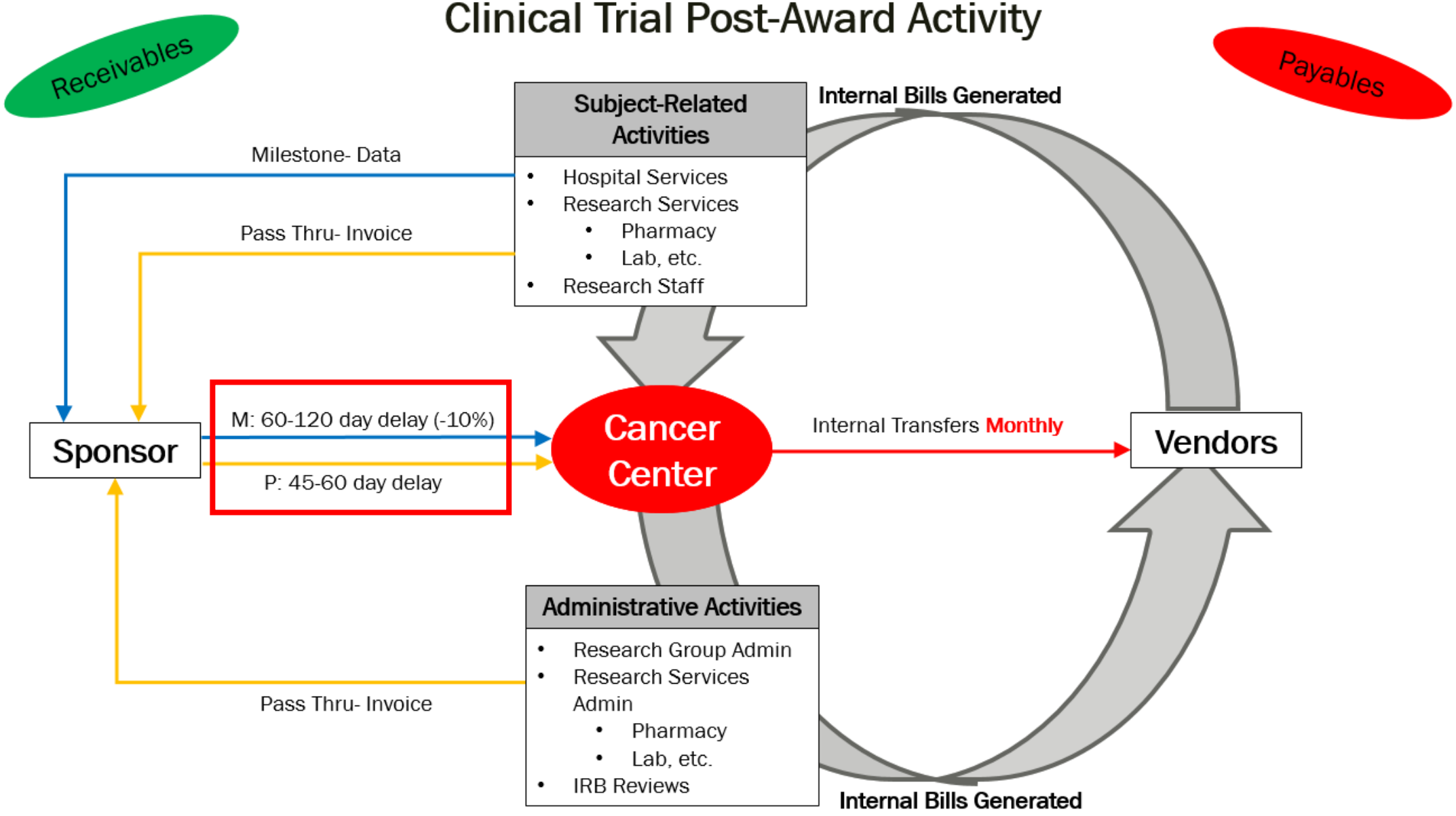
Budget Negotiation

- Budget draft- combine info from MCA, shared services, and research staff effort
- Negotiate with Sponsor/CRO
- Don’t forget payment terms!
- Execute contract
- Request Account in Advance (requires IRB approval as well)

Special Considerations for Clinical Trials

- WISPER and WISDM
  - Clinical Trials should have an **end date of 12/31/2099 in WISPER**- we don't know how long studies will take, and they don't have an "end date" like a grant.
  - **WISDM will show a budget of $0**- in a clinical trial, work must be done and invoiced before we receive any dollars. The budget will be increased to match the checks we receive, since that represents the work actually done.
  - Clinical trial **accounts often show a negative balance**- more active studies may have a higher negative balance. Charges for the work done are posted to WISDM in real time, but payment for that same work does not come until much later.

Clinical Trial Post-Award Activity



Invoicing

- Should be done at least quarterly
- Need to keep track of what needs to be invoiced
  - Start-ups: should be invoiced as soon as possible per the contract terms
  - Study events: admin fees, IRB reviews, PRC fees, etc.
  - Subject Visits: usually auto-paid based on data entered into sponsor's database ("Milestones")
  - Screen Failures
- Contract will say where to send invoices and what info needs to be included
- FOLLOW UP ON YOUR INVOICES!

Payments & Reconciliation

- Checks
  - May come to you or directly to campus accounting
  - Some don’t have details on what the payment is for- request this from sponsor
- Reconcile payments against amounts due
  - Invoices sent to sponsor
  - Internal invoices/list of items that should be auto-paid

Charge Review

- Review WISDM charges monthly to make sure charges are accurate
  - WISDM entries will be lump sums, will not show any composite charges
- Internal services can send breakdowns monthly
  - Shared Services- PRC, 3P, etc.
  - UWHC/UWMF- need to double-check to make sure everything was billed appropriately (study vs. insurance/subject)
- Develop internal tracking for reconciliation, AR, etc.

Campus Resources

- Oncology-related studies- UWCCC
- Office of Clinical Trials (OCT)
  - Regulatory, budget negotiation/contracts, invoicing, other
  - https://ictr.wisc.edu/groups/office-of-clinical-trials-oct/
- OnCore- used by UWCCC and ICTR to manage clinical trials
  - Calendar, IRB reviews, subject consent and treatment, finance
- Protocol Writing- offered through both UWCCC and ICTR
  - UWCCC: Sarah Stewart- slstewart@wisc.edu, 608/263-7898
  - ICTR: Tania Kamphaus- kamphaus@clinicaltrials.wisc.edu, 608/265-6663

Questions?

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