The Role of HIM in Clinical Research

Hollie Goddard
Sr. IRB Coordinator
McKesson Specialty Health

US Oncology Research
Health Information Management

- We are responsible for acquiring, analyzing, and protecting medical information vital to providing quality patient care.

- HIM professionals ensure the right information is available in a timely manner while maintaining the highest standards of data integrity, confidentiality, and security.

- These duties of HIM professionals are consistently found in coordinating a clinical study.
What is a Clinical Study?

A clinical study involves research using human volunteers (participants) that is intended to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions.
Some reasons for conducting clinical studies include:

- Evaluating one or more interventions (drugs, medical devices, surgery, radiation therapy) for treating a disease, syndrome or condition
- Finding ways to prevent the initial development or recurrence of a disease or condition (medicines, vaccines, lifestyle changes)
- Evaluating interventions that could identify or diagnose a particular disease or condition
- Examining methods for identifying a condition or the risk factors for that condition
- Exploring and measuring ways to improve the quality of life through supportive care for people with a chronic illness
There are two main types of clinical studies:

- clinical trials (also called interventional studies) and
- observational studies
Clinical Trials

- In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators or sponsors.
  - Interventions may include medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet.

- Clinical trials may compare a new medical approach to 1) a standard one that is already available, 2) to a placebo that contains no active ingredients, or 3) to no intervention.
Clinical Trials

- When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain outcomes in the participants.
  - For example, investigators give a treatment to participants who have high blood pressure to see whether their blood pressure increases or decreases.

- Clinical trials used in drug development are described by phases as defined by the Food and Drug Administration (FDA).
What are the Clinical Trial Phases?

- **Phase I**: Researchers test a new drug or treatment in a small group of people for the first time to evaluate safety, determine a safe dosage range, and identify side effects.

- **Phase II**: The drug or treatment is given to a larger group to see if it is effective and to further evaluate its safety.

- **Phase III**: The drug or treatment is given to large groups to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

- **Phase IV**: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.
Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Fulvestrant (Faslodex®) With or Without PD-0332991 Palbociclib)± Goserelin in Women with Hormone Receptor-Positive, HER2-Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Endocrine Therapy – Pfizer (A5481023)
Committee: Breast Cancer
Sponsor: Pfizer and Parexel (CRO)
Status: Closed to Enrollment
Sponsor accrual target: 417
USON accrual target: 44
Consented & Registered: 25
Currently 6 Active & 12 Follow-up Patients
8 Principle Investigators/Sites
2 Protocol Amendments
5 ICF Revisions
27 Deviations
6 Serious Adverse Events (None Related to Study Rx)
Observational Studies

In an observational study, investigators assess health outcomes by comparing subjects against a control group in cases where the investigator has no control over the experiment.

Types of Observational studies:
- Case–control study
- Cross–sectional study
- Longitudinal study
- Cohort study
- Ecological study

Participants may receive interventions or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial).
Main purpose – collect information on patients treated for metastatic breast cancer, and their response to the various treatments for this disease.

The investigator will provide information about patient’s history of metastatic breast cancer, results of tests done for cancer, and past treatments.

Every 3 months, the investigator will provide Genentech with information about ongoing treatment, results of tests, responses to treatment, and any complications.

Total study duration – 8 years.
Committee: Breast Cancer
Sponsor: Genentech & PPD
Status: Open to Enrollment
Sponsor accrual target: 1000
USON accrual target: 60
Consented & Registered: 48
Currently 45 Active & 0 Follow-up Patients
12 Principle Investigators/Sites
No Protocol Amendments or ICF Revisions
14 Deviations
7 Serious Adverse Events (None Related)
Like Health Information Management, patient safety and protection are the highest priorities in clinical trials. Every research study must follow a rigorous review and oversight process.

- Clinical trials are regulated and monitored by independent committees and federal agencies to ensure the study is safe and scientifically relevant.
- Informed consent is an ongoing process designed to protect the rights and safety of people participating in clinical trials.
- Participants may stop participating in a clinical trial at any time for any personal or medical reason, and they will continue to receive all necessary standard medical care.
The Belmont Report

- Created in 1974 by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- Identify the basic ethical principles and develop guidelines for research involving human subjects.
  - Respect for Persons
  - Beneficence
  - Justice

- Primary areas of application:
  - (i) the boundaries between biomedical and behavioral research,
  - (ii) assessment of risk–benefit criteria,
  - (iii) appropriate guidelines for the selection of subjects and
  - (iv) the nature and definition of informed consent
Good Clinical Practice

- Good clinical practice (GCP) is an international quality standard provided by The International Conference on Harmonisation (ICH), an international body that defines standards for clinical trials.

- Tight guidelines on ethical aspects of a clinical study are strictly enforced. High standards are required in terms of comprehensive documentation for the clinical protocol, record keeping, training, and facilities. Quality assurance inspections ensure that these standards are achieved.

- Protection of human rights for subjects and volunteers in a clinical trial. It also provides assurance of safety and efficacy of the newly developed compounds.

- Standards on how to conduct clinical trials and define the roles and responsibilities of sponsors, investigators, and monitors.
Informed consent is a process providing potential and enrolled participants with information about a clinical study. This information helps people decide whether they want to enroll or continue in the study.

The informed consent process is intended to protect participants and should provide enough information for a person to understand risks, benefits, and alternatives to the study.

A person must sign an informed consent document before joining a study to show that he or she was given information on risks, potential benefits, and alternatives and understands it.

Signing the document and providing consent is not a contract. Participants may withdraw from a study at any time.
Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by the FDA must be reviewed, approved, and monitored by an institutional review board (IRB).

The IRB’s role is to make sure that the study is ethical and that the rights and welfare of participants are protected.

Various Federal agencies, including the Office of Human Subjects Research Protection and the FDA, have the authority to determine whether sponsors of certain clinical studies are adequately protecting research participants.
What is an Institutional Review Board?

- According to FDA regulations, an Institutional Review Board (IRB) is a group formally designated to review and monitor biomedical research involving human subjects.

- An IRB has the authority to approve, require modifications in, or disapprove research.

- The IRB review serves an important role in the protection of the rights and welfare of human research subjects.
The purpose of IRB review is to assure, both initially in advance and by continuing periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research.

To accomplish this purpose, IRBs use a group process to review research protocols and related materials (informed consent documents, investigator brochures, protocol amendments) to ensure protection of the rights and welfare of human subjects of research.
2 Boards
- “Dallas” – 10 members
- “Houston” – 9 members

2 types of Meetings
- Weekly Expedited meetings
- Monthly Full Board meetings

A quorum must be established to begin the FB meeting. A quorum is one more than half members present, and one must be a nonscientific member.
- Oncologist (Chair) (S)
- Biostatistician (S)
- Nurse (S)
- Bioethics writer (S)
- Pharmacist (S)
- Attorney (NS)
- Chaplain (NS)
USO studies 2014: Dallas – 126, Houston – 128

[Bar chart showing the comparison between Houston and Dallas for different categories: Initial Studies, Closures/Final, Renewals, Modifications, SAE Reports, IDBs, SI/PI Translations, Deviation]
IRB Coordinator

- The IRB Coordinator primarily acts as a liaison between the IRB Committees and the Study Investigators or the sponsors via the Regulatory Affairs Department.

- The IRB Coordinator, under the direct supervision of the IRB Manager provides operational support, promotes ethical education and facilitates the functions of the IRB Committees.
Duties of the IRB Coordinator

- Initial and on-going training of IRB Committee members
- Review, modify and retain IRB SOPs and IRB Coordinator manuals
- Prepare and complete Committee annual reports
- Review and process of all submissions for IRB meetings
- Coordinate IRB meeting plans and teleconferencing needs
- Prepare meeting activities including: meeting agendas, member packets, meeting minutes, invoices, etc.
IRB Coordinator (cont.)

- Track the approval of regulatory submissions reviewed
- Post communications on the database management in CTMS
- Prepare renewal schedules and submission deadlines
- Prepare and maintain local and off-site storage
- Facilitate internal audits for process improvement
- Provide IRB education and mentorship to IRB, Regulatory Staff, site Investigators and research staff regarding IRB policies and procedures.
Responsibilities of the Regulatory Specialist

- Provide guidance to research site personnel and research central operations on regulatory affairs requirements and procedures.

- Review, analyze and amend study Informed Consent Forms and study Protocols.

- Maintain critical trial deadlines with sites and sponsors

- Request and maintain sponsor required documents – 1572s, FDQs, PSPs, IB Signature Pages.

- Index critical trial documents into ImageNow, our electronic storage and maintenance system
Regulatory Specialists (cont.)

- Coordinate visits for Monitors and provide them with access to trial documents for periodic review (Remote or on-site)

- Submit and obtain IRB approval and renewal of clinical protocols, IDBs, ICFs and other items required by IRB, trial sponsor or FDA

- Collect, review and process Serious Adverse Events, Drug Brochures and Investigational New Drug Safety Reports

- Maintain updated Investigator and Pharmacy CVs, MLs, DORs and Laboratory Ranges and CLIAs

- Coordinate new USO staff on-boarding, orientation and training

- Prepare projects and facilitate FDA and/or Sponsor audits
Regulatory Timeline

- Trial “flips” to Priority and Informed Consent is written
- Internal Consent review by Sr. Regulatory Specialist
- Consent review by Sponsor, PM, SI & Finance
- Study is submitted to IRB
  - Protocol
  - ICF
  - Investigational Drug Brochure (IDB)
  - Patient Materials (Advertisement, Educational, Recruitment)
  - USOR Scientific Committee Review Form
  - SI CV & Medical License
  - List of Principle Investigators
Regulatory Timeline (cont)

- FDQ Collection – 3 week deadline
- 1572/DRAP/PSP/IDB Page – 2 week deadline
- IRB Meeting/PI Approval
- Send complete packs to sponsor
- Sponsor review/Resolve outstanding documents
- Sponsor gives regulatory approval, PM opens site to study
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<th>3</th>
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<tbody>
<tr>
<td>Trial &quot;flips&quot; to Priority Status</td>
<td>Consent Review (Sponsor, SI, PM, Finance)</td>
<td>FDQ Collection</td>
<td>1572 DRAP collection</td>
<td>Sponsor review and approval of Regulatory documents</td>
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<td>Consent written / Internal Review</td>
<td>Submission to IRB</td>
<td>Collection reminder</td>
<td>Reminder</td>
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<td>Reminder</td>
<td>Calls with sponsor to resolve outstanding items</td>
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<td>TPR</td>
<td>IRB Meeting / PI Approval</td>
<td>Packs ship to sponsor</td>
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Other Roles at USO

- Project Manager (Clinical Trial Manager)
- Site Services
- Quality Assurance
- Finance/Budget
- Contracts/Legal
- Privacy and Safety
- Biomedical Writers
- Billing and AR
- Health Informatics
- IPC Distribution
- IT/CTMS support
Where do Clinical Research professionals work?

- Pharmaceutical companies (Sponsors)
  - Pfizer
  - Genetech
- Contract Research Organizations (CROs)
  - Parexel
  - Quintiles
- Site Maintenance Organization (SMO)
- Physician offices
- Hospitals
- Universities – research and education
- Medical device companies
The foundation of Clinical Research and Health Information Management strongly resemble one another

- Ensure that participant information is secure and protected
- Improve healthcare quality, reduce errors, and advance knowledge surrounding cancer treatment
- Provide appropriate information to help guide medical decisions at the time and place of care
- Improve the coordination of care and information among hospitals, labs, physician offices, pharma companies and other entities for secure exchange of cancer care information.
- Promote early detection, prevention, and management of cancer or chronic diseases
- Collect complete and accurate documents in a timely manner for clinical trials to ensure the best treatment decisions
Future Regulatory Endeavors

- E-signatures for investigator trial documents
  - Immediate processing by the regulatory team
  - Faster approval from the sponsor
  - Automatic storage in ImageNow
  - Guaranteed “legibility”
  - Accuracy and completeness

- Electronic IRB submissions
  - Electronic storage
  - Accuracy and completeness
  - More studies submitted and approved
Questions?