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Good Clinical Practice (GCP)

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Good Clinical Practice (GCP)

- A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials
- Includes review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study.

(21 CFR 312.120(a)(i))

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Purpose of GCP

- Protection of rights, safety, and welfare of study subjects
- Assurance of the credibility and accuracy of study data

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Sources

- 21 CFR 312.120 – Foreign clinical trials not conducted under an IND
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.120>
- ICH E6 Good Clinical Practice: Consolidated Guidance
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

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GCP: Overarching Themes

- Responsibility(-ies)
- Attention to Detail
- Documentation
- Quality
 - Data/Scientific Quality; Ethical Quality; Process Quality
- Risk and Risk Management
- Validation/Verification/Inspection

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The Goals of GCP –1

- Protecting Research Subjects
 - Subject safety
 - Rights as subjects (research ethics), including:
 - Right to be informed
 - Right NOT to participate
 - Right to withdraw at any time
 - Right to protection of privacy

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The Goals of GCP –2

- Ensuring the quality and integrity of research data for regulatory decision-making
 - Based on a scientifically sound protocol that is designed to meet its stated objectives
 - Based on the quality conduct and oversight of the clinical study

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The Goals of GCP –3

- Assuring the existence and operation of “quality systems”
 - Including but not just for the current study
 - By each party (investigator, sponsor, IRB/IEC, and regulatory authority)
 - Based on written procedures
 - Assured through self- and cross-evaluation
 - Leveraged: Regulatory authority can't do it all

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GCP – an international standard

- ICH E6
 - Used as law by some countries and adopted by many others
 - EU directive on clinical trials references it
 - Official FDA guidance
 - Covers some areas in more depth than FDA regulations (monitoring, auditing)
 - Covers some areas in less depth than FDA regulations (IRB/IEC responsibilities)

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FDA's GCP Regulations –1

- Regulations that cross products
 - 21 CFR Part 50 – Protection of Human Subjects
 - 21 CFR Part 56 – Institutional Review Boards
 - 21 CFR Part 54 – Financial Disclosure by Clinical Investigators
 - 21 CFR Part 11 – Electronic records; electronic signatures

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FDA's GCP Regulations –2

- Drugs and biologics
 - 21 CFR 312 – IND
 - 21 CFR 314 – New Drug Application (NDA)
 - 21 CFR 601 – Biologics License Application (BLA)
- Devices
 - 21 CFR 812 – Investigational Device Exemption (IDE)
 - 21 CFR 807, subpart E – premarket notification (510(k))
 - 21 CFR 814 – Premarket Application (PMA)
- Veterinary products
 - 21 CFR 511 – New Animal Drugs for Investigational Use
 - 21 CFR 514 – New Animal Drug Application (NADA) ¹¹

Responsible Parties Under GCP

- Study sponsor/monitor/contract research organization (CRO)
- Clinical investigator(s) (CIs)
- Institutional Review Board (IRB)/ Independent Ethics Committee (IEC)
- Regulator(s)

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Shared Responsibilities

- Responsibilities overlap – system of checks and balances
- Each party independently responsible for compliance
- FDA regulations and ICH E6 comparable in this regard

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Sponsor

- *Sponsor* means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.

21 CFR 312.3(b) (similar definitions in 812.3(n) and 511.3)

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Sponsor

ICH E6

- **1.53 Sponsor:** An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

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Sponsor Responsibilities –1

- Obtain regulatory approval, where necessary, before initiating a study
- Manufacture and label investigational products appropriately
- Initiate, withhold, or discontinue studies as required
 - Includes protocol development, often in consultation with one or more clinical investigators

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Sponsor Responsibilities –2

- Refrain from commercialization of investigational products
- Control the distribution and return of investigational products
 - Detailed records
 - Proof of IRB/IEC approval before initial shipment
- Select qualified clinical investigators
 - Credentials can vary by study & country requirements
 - “1572” commitments for pharmaceutical studies
 - Investigator agreements for medical device studies

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Sponsor Responsibilities –3

- Disseminate appropriate information to investigators
 - Commonly = Investigator’s Brochure for pharmaceutical studies
 - Update as necessary
- Select qualified persons to monitor the conduct of the studies

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Sponsor Responsibilities –4

- Adequately monitor clinical studies
 - Written SOPs desirable (required by FDA device regulation)
 - Requires access to site and subject records (privacy laws applicable)
 - Provides quality control – for assurance of subject protections and data integrity
 - Enables assurance of clinical investigator compliance

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Sponsor Responsibilities –5

- Evaluate and report adverse experiences
- Maintain adequate records
 - Retention according to regulatory requirements
- Submit all reports, including safety reports, annual/progress and final reports, as required

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Clinical Investigator

- *Investigator* means an individual who actually conducts a clinical investigation (*i.e.*, under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

21 CFR 312.3(b) (similar definitions in 812.3(i) and 511.3)

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Clinical Investigator

ICH E6:

- **1.34 Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- Suggests an investigator at each site; multisite study may have a coordinating investigator, but there should be a responsible party at each site

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Investigator Responsibilities –1

- Personally conduct and/or supervise the study
 - Cannot contract out any responsibilities; is entirely responsible for study conduct at site
 - Needs to ensure qualifications and training of anyone delegated study duties and meet with study staff on a regular basis
 - SOPs for site's conduct of studies and handling of problems – not required by FDA regulations

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Investigator Responsibilities –2

- Communicate with the IRB/IEC
 - Initial approval before initiation of study
 - Amendments/progress reports/continuing review
 - "Safety" reports
- Ensure proper informed consent process
 - IRB/IEC approved form
 - Documented prior to any study-related activities
 - If delegated, only to appropriate study staff

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Investigator Responsibilities –3

- Protocol compliance
 - No deviation without prior sponsor and IRB/IEC approval – unless to eliminate an **immediate** hazard to subjects
 - Protocol should be designed to facilitate compliance
- Control of investigational products
 - Detailed records – receipt, use, & disposition
 - Proper storage and handling – as defined in the protocol

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Investigator Responsibilities –4

- Where applicable - maintenance of randomization and blinding; unblinding only for medical emergencies and then fully documented
- Safety reporting
 - Recognizing and reporting all adverse events
 - Special attention to serious and unexpected events – reporting to sponsor and IRB/IEC and regulatory bodies as required

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Investigator Responsibilities –5

- Recordkeeping
 - Accurate and complete case histories for each study subject – both those to whom investigational product was administered and controls
 - Includes
 - Source documents (hospital charts, clinical laboratory reports, x-rays, ECGs, subject diaries, pharmacy records)
 - Case report forms
 - Correspondence
 - Other study-related documents – e.g., protocol, with all amendments; Investigator's Brochure, screening logs

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Investigator Responsibilities –6

- Recordkeeping (cont.)
 - Quality and integrity of data essential
 - Maintained as required by applicable regulations

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Investigator Responsibilities –7

- Reporting
 - Safety reports
 - Progress reports
 - To sponsor
 - To IRB/IEC for continuing review
 - Final report

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Investigator Responsibilities –8

- Medical care of study subjects: FDA guidance on Investigator Responsibilities – <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>
 - Providing reasonable medical care for study subjects for medical problems that are or could be related to the study intervention
 - Providing reasonable access to needed medical care, either by the investigator or by another identified, qualified individual
 - Adhering to the protocol so that study subjects are not exposed to unreasonable risks

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Investigator Responsibilities –9

- Medical care of study subjects (ICH/WHO)
 - Ensure access to reasonable standard of care
 - Investigator or other medically qualified member of study team
 - Recommends informing subject's primary physician of participation in the study

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IRBs/IECs

- *Institutional Review Board (IRB)* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase *institutional review committee* as used in section 520(g) of the act.

21 CFR 56.102(g)

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IRBs/IECs

ICH E6:

- **1.27 Independent Ethics Committee (IEC):** An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and nonmedical/nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

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Role of IRB/IEC –1

- Safeguarding the rights, safety, and welfare of all actual or potential research participants
- Providing substantive **independent**, competent, and timely ethical review of the proposed study, initially and on a continuing basis (institutions cannot reverse an IRB's negative decision)
- Considering both the scientific and ethical aspects of the study – scientifically unsound research is not ethical

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Role of the IRB/IEC –2

- Ensure
 - Risks to subjects are minimized
 - Risks are reasonable in relation to anticipated benefits
 - Selection of subjects is equitable
 - Informed consent is appropriately conducted and documented
 - Subject safety is adequately monitored
 - Subject privacy is adequately addressed

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IRB/IEC Responsibilities

FDA regulations (21 CFR Part 56) and ICH E6 address the following areas:

- Membership
- Documents necessary for review
- Scheduling and documenting meetings
- Written procedures
- Ethical review (including informed consent – as required by 21 CFR Part 50 for FDA)
- Decision-making
- Communicating a decision
- Continuing review
- Documentation and archiving

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Regulator's Role

- Regulatory authorities should operate transparently, following SOPs and due process to:
 - Allow protocols to proceed (IND/IDE approval for FDA)
 - Ensure the quality of the investigational product
 - Ensure the rights, safety, and welfare of study subjects
 - Ensure data quality adequate for decision-making
 - Respond to complaints
 - Inspect and educate

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FDA Inspections of Clinical Studies

COMPLIANCE PROGRAMS

- Guidance for HQ and field regarding
 - Issuance of inspection assignments
 - Conduct of inspections
 - Post-inspectional options
- Programs are Agency-wide (available through <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm160670.htm>)
- Center-specific differences are included where applicable

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Product-specific considerations

- Differences in inspection instructions stem from differences among the products:
- Pharmaceuticals versus devices:
 - Nature of product, firms, and studies
 - Statutory distinctions
 - Regulatory distinctions

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Nature of product

<p>Pharmaceuticals (drugs & biologics)</p> <ul style="list-style-type: none"> Molecular entities Limited shelf life Long market life Potential for interactions with other drugs Wrong drug/dose issues 	<p>Devices</p> <ul style="list-style-type: none"> Complex components Many = durable equipment Short product cycles – “tweaking” of design Device malfunctions User errors
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Nature of firms

<p>Pharmaceuticals</p> <ul style="list-style-type: none"> Large, often multi-national firms Extensive clinical trial experience 	<p>Devices</p> <ul style="list-style-type: none"> Entrepreneurial firms common Device “developer” often involved Many have minimal clinical trial experience Sponsor-investigators common
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Studies

<p>Pharmaceuticals</p> <ul style="list-style-type: none"> Nonclinical <ul style="list-style-type: none"> toxicology Clinical <ul style="list-style-type: none"> subject populations commonly 1000s phases routinely blinded placebo = common control 	<p>Devices</p> <ul style="list-style-type: none"> Nonclinical <ul style="list-style-type: none"> biocompatibility (+ bench/mechanical testing) nonclinical studies may suffice Clinical <ul style="list-style-type: none"> subject populations usually 100s pilot study possible + pivotal blinding less common “controls” vary CI training often critical (Human Factor concerns)
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Statutory Distinctions

- Pharmaceutical marketing exclusivity provisions
 - Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) made permanent under FDASIA (2012)
 - Orphan drug tax exemptions (drugs/biologics)
- FDAMA (1997) – “least burdensome” provision for devices; continued under FDASIA
- FDASIA (2012) – profits allowed for HDEs – expanded beyond pediatric products and even to some previously approved HDE products

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Regulations

Pharmaceuticals	Devices
<ul style="list-style-type: none"> 21 CFR Part 312 – IND Part 314 – NDA Part 600 – general biologics provisions Part 601 – BLA 	<ul style="list-style-type: none"> 21 CFR Part 812 – IDE Part 809 - IVDs Part 814 – PMA Part 807, Subpart E – 510(k)

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Regulatory distinctions -1

Pharmaceuticals	Devices
<ul style="list-style-type: none"> Adequate, well-controlled trials CROs – 312.52 = transfer of regulatory obligations Form FDA 1572 FDA agreement not usually required before enacting study changes AE reports during study may use Form 3500A (Med Watch) – 312.32(c)(1)(v) 	<ul style="list-style-type: none"> Valid scientific evidence CROs – regulations silent save for definition of monitor [812.3(j)] Investigator agreement [812.43(c)] Significant study changes require IDE supplement approval AE reports during study not to go to MedWatch (i.e., not use MDR)

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Regulatory distinctions -2

Pharmaceuticals	Devices
<ul style="list-style-type: none"> Manufacturing – cGMPs – Parts 210 & 211 + Part 606 for blood & blood products MedWatch reports for approved pharmaceuticals are voluntary 	<ul style="list-style-type: none"> Manufacturing – Part 820 (QSR) MDRs for approved devices are mandatory – Part 803

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Additional Device Distinctions

- Classes of Devices** – risk-based determination
 - 21 CFR 860 – classification procedures
 - 21 CFR 862 through 892 – specific device classifications by product type

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Additional Device Distinctions

- Cleared devices** – 510(k)
 - 21 CFR 807, subpart E – Premarket Notification Procedures
 - “substantially equivalent”
- Approved devices**
 - 21 CFR Part 814
 - PMA, PDP, HDE
 - Safety and effectiveness – PMA & PDP
 - Safety and probable benefit – HDE

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Additional Device Distinctions

- Significant risk/non-significant risk (SR/NSR) studies
- Exempt studies/in vitro diagnostics (IVDs)
- Protocol and device changes; 5-day notices

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Significant Risk

Regulatory definition (21 CFR 812.3(m)) – device that presents potential for serious risk to health, safety, or welfare of a subject, particularly if it

- Is intended as an implant;
- Is purported or represented for use in supporting or sustaining life;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or
- Otherwise presents a potential for serious risk to health, safety, or welfare of the subject.

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NSR Studies

- NSR status based on use of the device in the study, not on the device alone
- Sponsor makes initial assessment
- IRB makes determination
- FDA can disagree
- If NSR study, no IDE application to FDA
- Informed consent required
- Abbreviated requirements apply (21 CFR 812.2(b))
- Considered to have an IDE

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Exempt device studies

- 21 CFR 812.2 (c)
- Studies with cleared devices, used as specified in clearance
- Extended to approved devices, with same conditions
- Diagnostic devices that meet requirements specified – includes IVDs, referencing labeling conditions of 809.10

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In Vitro Diagnostics (IVDs)

SR/NSR/exempt studies

Exempt if:

- labeled according to 21 CFR 809.10
- noninvasive
- noninvasive sampling or no significant risk
- does not introduce energy into a subject
- not used as the diagnostic for determination of treatment

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Significant Risk IVD Studies

- If study involves invasive sampling that presents a significant risk
- If results from use of an investigational IVD will determine treatment, could inaccurate results:
 - be life-threatening
 - result in permanent functional impairment
 - result in permanent structural damage
 - necessitate medical or surgical intervention to prevent impairment or damage

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IVD Studies & HSP Issues

- Studies on specimens – included in device definition of a subject (812.3(p))
- Expedited review by IRB possible
- Confusion with 45 CFR Part 46
- Privacy & confidentiality
- FDA data audits

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In Vitro Diagnostics (IVDs)

- Guidance on use of left-over specimens not individually identifiable –
 - issued April 25, 2006 –
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078384.htm>

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IDE Protocol Changes -1

IDE Supplement required if changes significantly affect:

- validity of data
- scientific soundness of study
- rights, safety, or welfare of subjects

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IDE Protocol Changes -2

Examples when supplement required:

- indication change
- different type of study control
- alternative primary endpoint
- reduction in study population size
- change in method of evaluation
- early termination of the study

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5-Day Notice

1998 amendment to Part 812 – covers:

- developmental changes to the device that do not constitute a significant change in design or basic principles of operation
- protocol changes that do not meet requirements for an IDE supplement – for example:
 - additional measurements
 - more targeted subject criteria
 - more frequent follow-ups
 - change in secondary endpoints

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GUIDANCE DOCUMENT – issued by Office of Device Evaluation (ODE)

Changes or Modifications During the Conduct of a Clinical Investigation - issued May 29, 2001

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082145.htm>

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BIMO Program

Comprehensive program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research

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BIMO Program Objectives

- Protect the rights, safety, and welfare of subjects in FDA-regulated trials
- Determine the accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications; and
- Assess compliance with FDA's regulations governing the conduct of clinical trials, including those for informed consent and ethical review

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BIMO at the Centers –1

- Specific group in each Center to oversee BIMO program
 - Bioresearch Monitoring Branch/Division of Inspections and Surveillance/Office of Compliance – CBER
 - Office of Scientific Investigations (OSI)/Office of Compliance - CDER
 - Division of Bioresearch Monitoring (DBM)/Office of Compliance – CDRH
 - Pre-Market Compliance & Actions Team/Division of Compliance/Office of Surveillance & Compliance - CVM

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BIMO at the Centers –2

See specific Center contact information under “Good Clinical Practice Contacts” link on our website

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm>

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BIMO at the Centers –3

Headquarters BIMO staff:

- Interact with Center reviewers
- Issue inspection assignments
- Interact with ORA BIMO investigators
- Review and classify EIRs
- Issue post-inspectional correspondence
- Initiate regulatory actions (AIP, DQ)
- Conduct ORA BIMO investigator training
- Conduct educational outreach

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Office of Good Clinical Practice (OGCP) –1

- FDA lead for HSP/BIMO policy development
- Heads the HSP/BIMO Council (Director serves as Council Chair)
 - Serves as FDA's focal point regarding GCP issues in human research trials
 - Coordinates FDA human subject protection (HSP) and GCP policies
 - Coordinates the bioresearch monitoring (BIMO) program

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OGCP –2

- Plans and conducts training and outreach programs
- Serves as liaison with the Office for Human Research Protections (OHRP), other federal agencies, and external stakeholders with a commitment to HSP
- Contributes to international GCP harmonization activities

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HSP/BIMO Council –1

- Chair – Director of the Good Clinical Practice Program (OGCP)
- Executive Secretary – provided by the Office of the Commissioner
- Representatives from each Center (CBER, CDER, CDRH, CFSAN, CVM, NCTR), ORA, & OC

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HSP/BIMO Council –2

- Supports Working Groups (WGs) – long-standing and ad hoc
- Reviews policy and guidance relevant to GCP/HSP issues and the BIMO program
- Serves as an advocate for HSP/GCP and BIMO-related regulations and guidance

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Resources –1

- GCP website – <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>
- Accessible via:
 - Alias – www.fda.gov/gcp
 - Good Clinical Practice link in A-Z index for FDA home page

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Resources –2

- GCP queries e-mail account (about 1,200 queries answered per year) – gcp.questions@fda.hhs.gov
- Previous queries (2002 – 2011) – “Replies to queries...” link from GCP website (bottom of left-hand column)
- Listserve – via GCP website – notice of updates on FDA’s GCP/HSP activities

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OGCP Staff

- **Joanne Less – Director**
- Janet Donnelly
- Bridget Foltz
- Sara Goldkind
- Doreen Kezer
- Marsha Melvin
- Patrick McNeilly (as of February 1, 2013)
- Kathleen Pfaender
- Jean Toth-Allen

Contact information available in HHS Outlook address book

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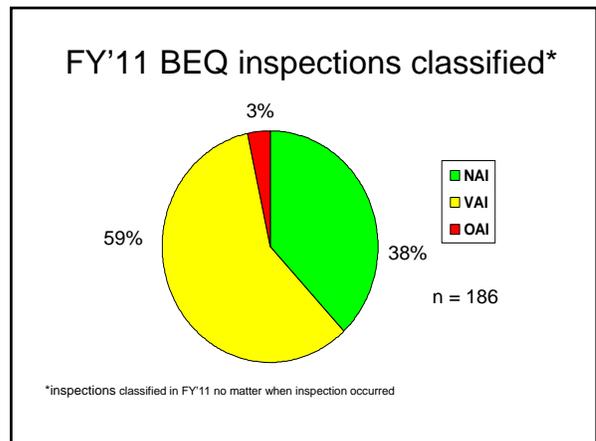
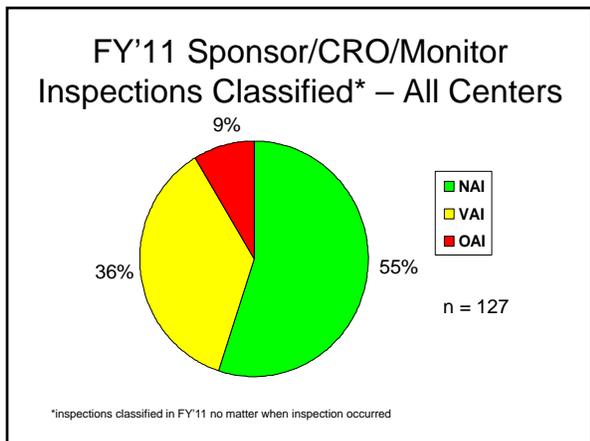
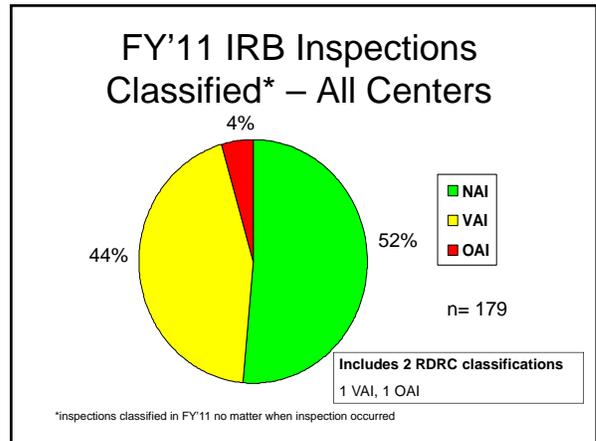
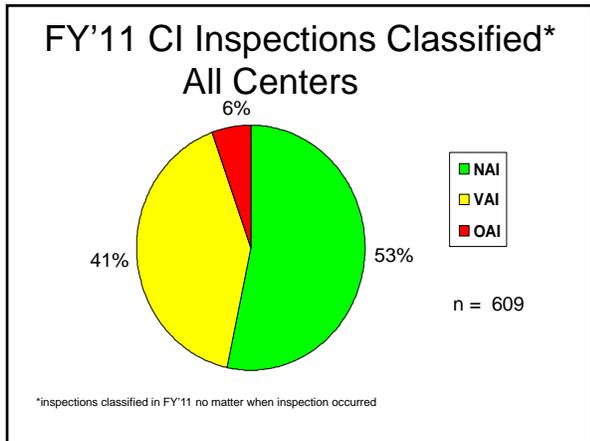
BIMO inspection metrics

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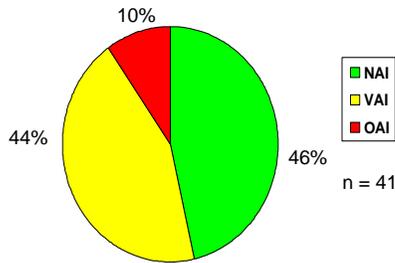
BIMO Inspections Completed FY 2011

Center	CI	IRB	Spon/Mon	GLP	Total
CBER	62	22	12	3	99
CDER*	315	103	44	27	489
CDRH	173	62	78	8	321
CFSAN**	0	0	0	0	0
CVM	26	na	6	7	39
All Centers	576	187	140	45	948

* 3 IRB = RDRC; + 194 BEQ inspections (CDER specific)
 ⇨ total = 1142
 ** CFSAN's BIMO Program is under reorganization



FY'11 GLP inspections classified* All Centers

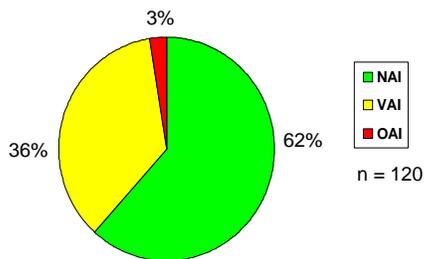


*inspections classified in FY'11 no matter when inspection occurred

International Inspections Completed: FY 2011

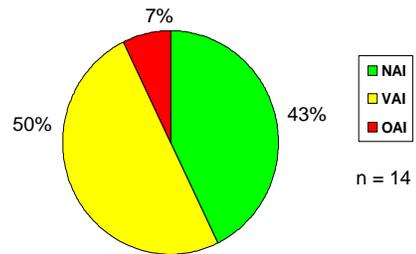
Center	CI	Sponsor	GLP	BEQ	Total
CBER	8	1			9
CDER	100	7		99	206
CDRH	13	3	1		17
CVM		1			1
Totals	121	12	1	99	233

FY'11 International CI Inspections Classified* – All Centers



*inspections classified in FY'11 no matter when inspection occurred

FY'11 International Sponsor/CRO/Monitor Inspections Classified* – All Centers



*inspections classified in FY'11 no matter when inspection occurred

Other International Inspections Classified in FY'11*

GLP

- CDRH – 1 – OAI

BEQ

- CDER – 87 – 25 NAI, 62 VAI

*inspections classified in FY'11 no matter when inspection occurred

Thank You!

Further Questions?