Clinical Data Management: Strategies for unregulated data

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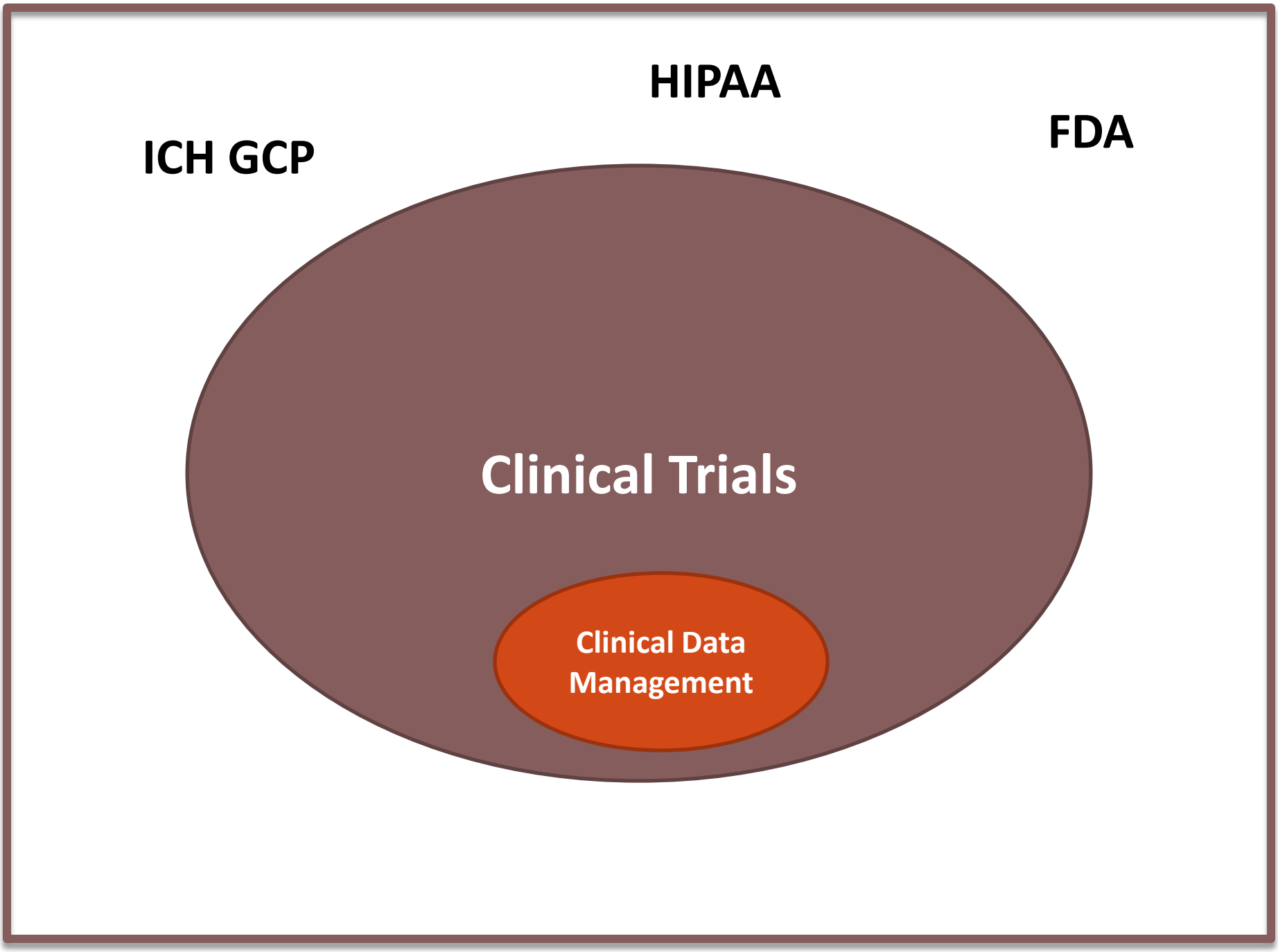
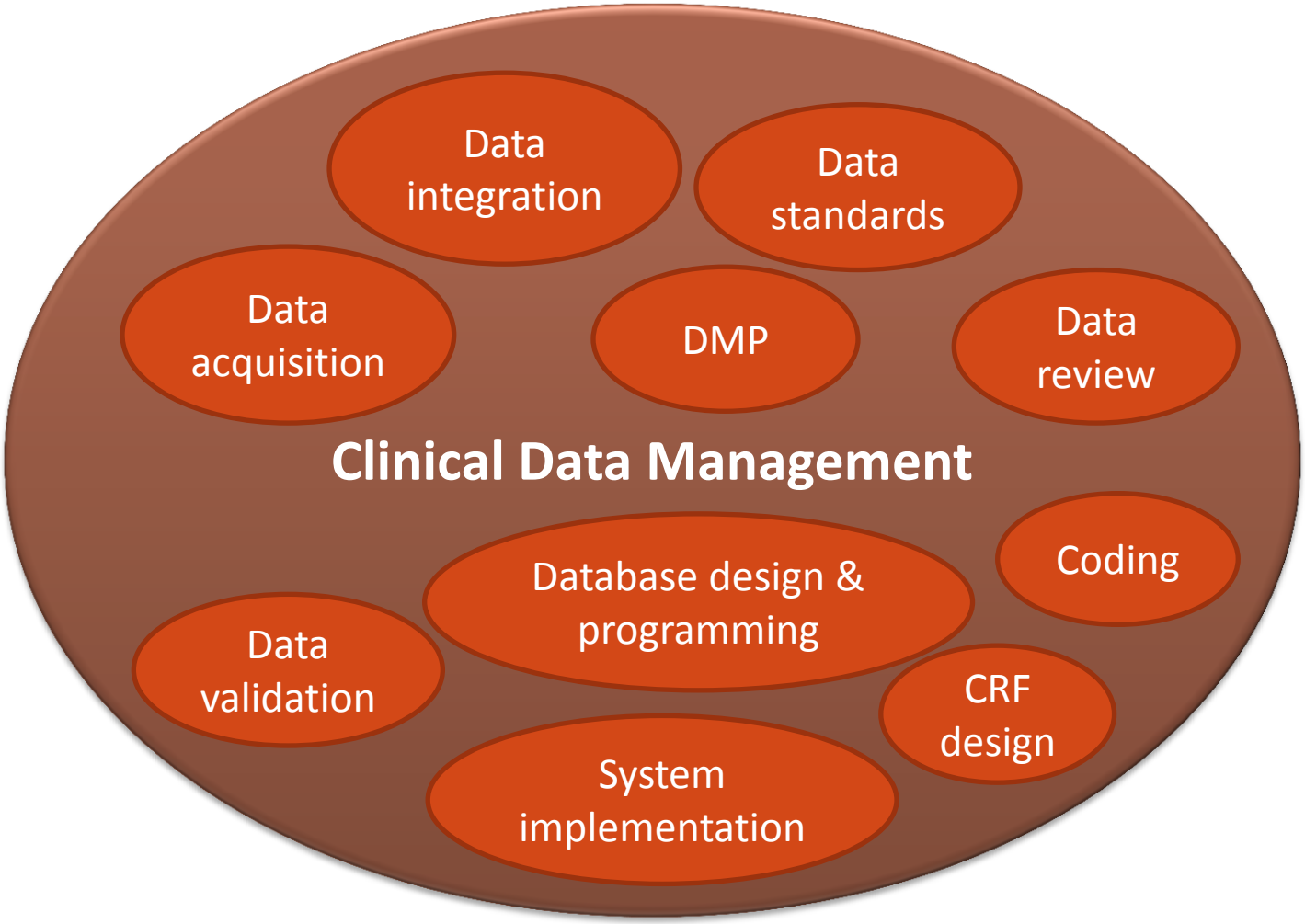

HIPAA
FDA
ICH GCP
Clinical Trials
Clinical Data Management

Regulation → Standard Practice

- Efficiency
- Efficacy*
- Safety*
- Accuracy
- Confidentiality/Privacy*

- Clear expectations
- Standards
- Best practices established

- Burdensome
- Inflexible
- Expensive


Data integration
Data standards
Data acquisition
DMP
Data review
Clinical Data Management
Coding
Database design & programming
Data validation
CRF design
System implementation

Good Clinical Data Management Practices

- 20 areas in 2011 document
- General themes
  - Plan, test, revise, test…implement
  - All stakeholders involved in design of protocol, data collection tools, data management plan, etc.
  - Document, document, document
  - Rule: the bigger the study (sites, data, people), the more planning you need

Good Clinical Data Management Practices

- Specify documents required for reproducible research
  - Organization: SOP
  - Study: Protocol, Manual of procedures, Data management plan, Statistical analysis plan
- Documentation serves practical purposes and benefits the team immediately
- Allows specification of roles and responsibilities from the beginning

Good Clinical Data Management Practices

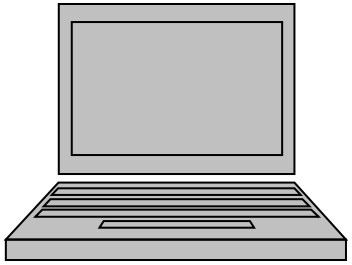
Begin with the end in mind OR
Produce report-ready output

Collect data in a way that allows for efficient data entry, processing, validation, and analysis

Enabled by standardized data collection tools (CRF)

Case Report Forms (CRF)

- Efficient (concise)
- Effective (clear)
- Minimize redundancy
- Minimize human error – consider completeness, accuracy, legibility, timeliness
- Enables fast data transfer across studies



Raw data

Processed data

Analysis

Protocol number BIG 2-06 / NCCTG N063D / EGF106708 **Scree**

Centre No. ☐☐☐☐☐☐ Subject No. ☐☐☐☐☐☐ Pag

Vital signs and physical measurements

Date of physical exam ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

Physical exam
- ☐ Normal
- ☐ Abnormal - Not clinically significant
- ☐ Abnormal - Clinically significant → *Specify abnormality in "Previ or current diseases" page 15*

Height (cm) ☐☐☐

Weight (Kg) ☐☐☐.☐

BSA (m^2) ☐.☐☐

Blood pressure ☐☐☐ / ☐☐☐ mmHg (systolic / diastolic)

Heart rate (beats/min) ☐☐☐

ECOG performance status ☐

EKG

Date of EKG ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

Result
- ☐ Normal
- ☐ Abnormal - Not clinically significant
- ☐ Abnormal - Clinically significant → *Specify in "Previous or curre cardiovascular diseases" pa*

LVEF

Date of LVEF ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

LVEF (patient value) ☐☐.☐ % Method of evaluation ☐ Echocardiogram ☐ MUGA scan

- ☐ Normal
- ☐ Abnormal - Not clinically significant
- ☐ Abnormal - Clinically significant → *Specify in "Previous or curre cardiovascular diseases" pa*

Symptomatic CHF
- ☐ No
- ☐ Yes → *Specify below*

NYHA classification
- ☐ Class I *(asymptomatic, tick No for the question above)*
- ☐ Class II
- ☐ Class III
- ☐ Class IV

State of California - Health and Human Services Agency

Reset Form | Print Form

ADULT HIV/AIDS CONFIDENTIAL CASE REPORT
(Patients ≥ 13 years of age at time of diagnosis)

California Department of Public Health
Office of AIDS
HIV/AIDS Surveillance Program

I. This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.

Patient's name (last, first, MI) | Telephone number | Social Security Number

Address (number, street) | City | County | State | ZIP code

Date form complete Month Day Year | Report Status: 1 New, 2 Update | Report Source

II. *Health Department Use Only*

Reporting health department | State patient number | City/county patient number

Soundex code | Date of Birth (Month, Day, Year) | Gender: 1 M, 2 F, 3 M ▸ F, 4 F ▸ M | CLIA number | Lab report/Accession number | *Confidential C&T number

*Publically funded confidential counseling and testing sites only

III. Demographic Information

Diagnosis status at report (check one): 1 HIV Infection (not AIDS), 2 AIDS | Age at Diagnosis Years | Current status: 1 Alive, 2 Dead, 9 Unknown | Date of death (Month, Day, Year) | State/Territory of death

Country of birth: 1 U.S., 7 U.S. Territories (including Puerto Rico), 8 Other (specify):, 9 Unknown

ETHNICITY: 1 Hispanic, 2 Not Hispanic nor Latino

RACE: American Indian/Alaskan Native; Black or African Amerian; Asian; Native Hawaiian/Other Pacific Islander; White; Unknown

Expanded race (specify):

☐ Check if HIV infection is presumed to have been acquired outside United States and Territories. Specify country:

Residence at first diagnosis of HIV or AIDS: ☐ Homeless (Must use city/county/ZIP code of local health department (LHD) or facility of diagnosis.)

City | County | State/Country | ZIP code

IV. Facility of Diagnosis

Facility name | City | State/Country

Facility setting (check one): 1 Public, 3 Federal, 2 Private, 9 Unknown

Facility type (check one): 01 Physician, HMO; 22 Counseling and Testing Site; 29 Community Health Center; 30 Correctional Facility; 31 Hospital, inpatient; 32 Hospital, outpatient; 88 Other (specify):; 99 Unknown

V. Patient Risk History (Check all that apply.)

	Yes	No	Unknown
Sex with a male	1	0	9
Sex with a female	1	0	9
Injected nonprescription drugs	1	0	9
HETEROSEXUAL relations with any of the following:	Yes	No	Unknown
Intravenous/injection drug user	1	0	9
Bisexual male	1	0	9
Person with hemophilia/coagulation disorder	1	0	9
Transfusion recipient with documented HIV infection	1	0	9
Transplant recipient with documented HIV infection	1	0	9
Person with AIDS or documented HIV infection, risk not specified	1	0	9

Received clotting factor for hemophilia/coagulation disorder — Yes 1 / No 0 / Unknown 9

Specify disorder: 1 Factor VIII (Hemophilia A), 2 Factor IX (Hemophilia B), 8 Other (specify):

Received transfusion of blood/components (other than clotting factor) Month Year — First: Last: — Yes 1 / No 0 / Unknown 9

Received transplant of tissue/organs or artificial insemination — Yes 1 / No 0 / Unknown 9

Worked in a health care or clinical laboratory setting (Specify occupation): — Yes 1 / No 0 / Unknown 9

Perinatally-acquired HIV infection regardless of year of birth — Yes 1 / No 0 / Unknown 9

Other (specify): — Yes 1 / No 0 / Unknown 9

VI. Laboratory Data (Indicate first documented test(s).)

A. HIV Antibody Test at Initial HIV/AIDS Diagnosis — Month Day Year

HIV-1 EIA

HIV-1/HIV-2 combination EIA

Rapid HIV-1 EIA

HIV-1 Western Blot/IFA

Other HIV antibody test (Specify):

B. *Positive* HIV Detection Test (Record earliest test.) — Month Day Year

☐ Culture ☐ Antigen ☐ DNA PCR ☐ RNA PCR

☐ Other (specify):

Date of last documented ***negative*** HIV test — Month Day Year

Specify type:

Specify facility type (use codes in Section IV): 01 22 29 30 31 32 99 88 (Specify):

If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? Yes 1 / No 0 / 9

If yes, provide date of documentation by physician — Month Day Year

C. HIV Viral Load Test *(Record earliest test.)* — Month Day Year

Test type*: Version*:

Other (specify type and version):

Test result *(Record in copies/mL **and** log10 values.)*

☐ Detectable — Copies/mL: / Log10: / Greater than: copies/mL:

☐ Undetectable — Less than: copies/mL:

*Test type and version: 11=NucliSens® HIV-1 QT (Organon-NASBA); 12=Amplicor HIV-1 Monitor® (Roche-RT-PCR), version: 1.0 or 1.5; 13=Bayer/Chiron (bDNA), version: 2.0 or 3.0; 18=Other (kit name/manufacturer/version)

D. Immunologic Lab Tests - At or closest to current diagnosis status

CD4 count: cells/µl — Month Day Year

CD4 percent: %

First <200 µl or <14%

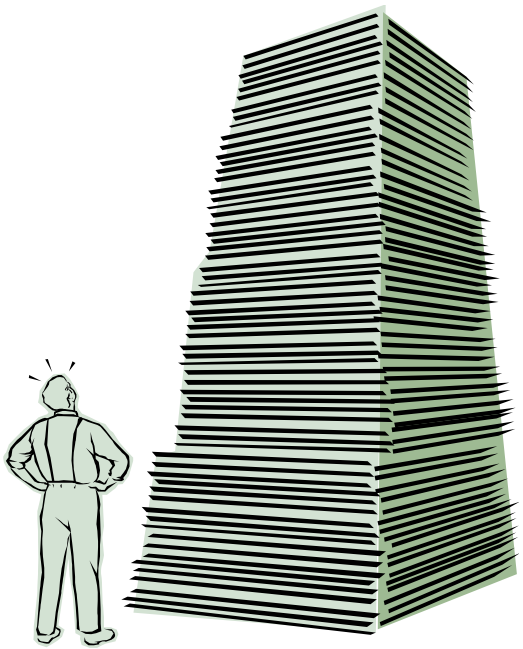
CD4 count: cells/µl — Month Day Year

CD4 percent: %

Checklist

+

Form



CRF + Instructions = CRF Book

Why do these strategies work?

- Save time and money
- Regulated environment – compliance is enforced
- Clinical trials are similar in structure and question are fairly narrow in scope

BUT!!!

- GCDMP provide practical strategies that meet regulatory requirements

References & Resources

1. Society for Clinical Data Management. (2011). Good Clinical Data Management Practices. Washington, D.C.
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