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## DataFax and Good Clinical Practice (GCP) Guidelines

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### Which GCP Guidelines?

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- Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance  
<http://www.fda.gov/cder/guidance/959fnl.pdf>
- Developed by ICH, FDA in April 1996
- International ethical and scientific quality standard for designing, conducting, recording, and reporting trials involving human subjects

## Areas of GCP Relevant to DataFax

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### Data management:

1. trial management; data handling; record keeping (2.10; 5.5.3a-d)
2. subject and data confidentiality (2.11; 5.5.3g\*)
3. safety reporting (4.11)
4. quality control (4.9.1; 4.9.3; 5.1.3)
5. records and reports (5.21\*; 5.22)
6. monitoring (5.5.4\*)

\* = DataFax does not assist

## Areas of GCP Not Relevant to DataFax

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### Non-data management:

1. IRB/IEC
  2. investigator qualifications; monitor selection; investigational products
  3. trial protocol; investigator's brochure
  4. subject consent; medical care; randomization
  5. trial financing
  6. audits
- This is the majority of the GCP's coverage

## Focus of Presentation

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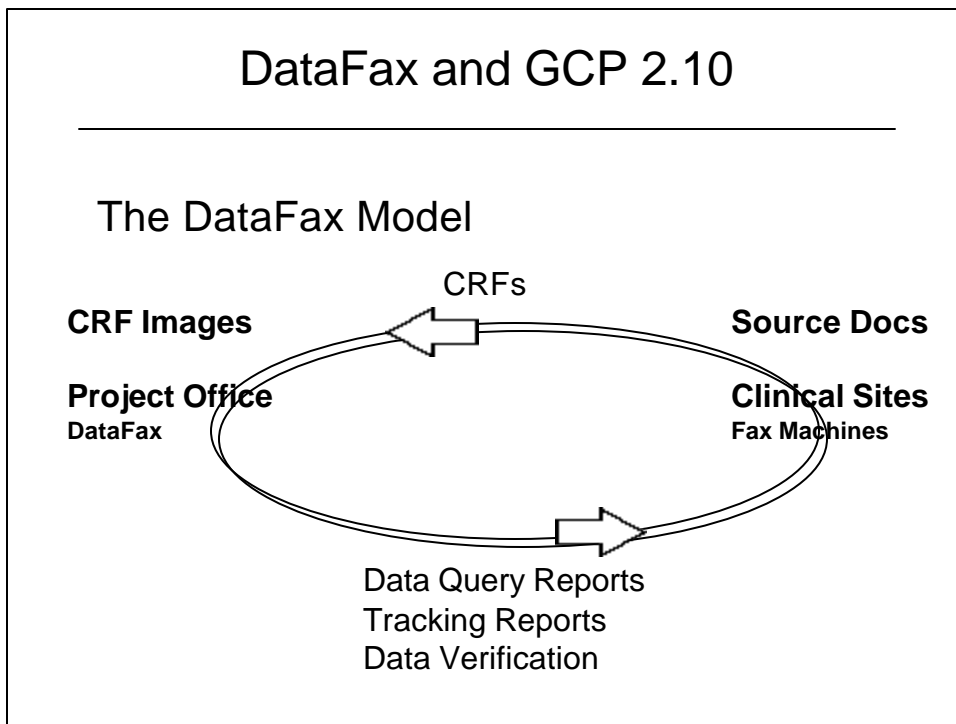
How does DataFax assist/not assist(\*)  
with data management issues outlined in  
the GCP Guidelines?

## 1. Trial Management

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### GCP 2.10

“All clinical trial information should be  
recorded, handled, and stored in a way  
that allows its accurate reporting,  
interpretation, and verification.”



### 1. Trial Management

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**GCP 5.5.3 a**  
“Ensure and document that the electronic data processing system(s) conforms to the sponsor’s established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).”

## DataFax and GCP 5.5.3 a

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- DataFax Acceptance Test Kit (ATK) provides a partial system validation plan
  - verifies main functionality of DataFax
  - assists users to validate DataFax in their own environment
  - provides documentation of the validation plan
- You still need your own requirements and additional validation

## 1. Trial Management

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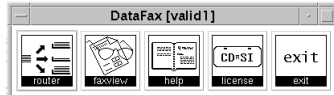
### GCP 5.5.3 b

“When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should maintain SOPs for using these systems.”

## DataFax and GCP 5.5.3 b

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- Online help is available for all DataFax tools



- DataFax documentation includes sample SOPs
  - study setup worksheets
  - workflow and data management
  - study closeout

## 1. Trial Management

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### GCP 5.5.3 c

“Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).”

## DataFax and GCP 5.5.3 c

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- Corrections to data are made on source documents at the site and re-faxed
- DataFax recognizes and stores duplicate CRFs and records
- Audit trails are kept for database modifications and validation history of faxes
- DataFax does not delete/alter any CRF images
- DataFax does not insert data values

## 1. Trial Management

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### GCP 5.5.3 d

“Maintain a security system that prevents unauthorized access to the data.”

## DataFax and GCP 5.5.3 d

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- System login name and password are required
- Users must be registered for a DataFax study
- Users must have permission for a specific tool
- Each user is assigned a maximum validation level at which they can work
- Supplement this with a paper trail of authorization changes

## 2. Subject & Data Confidentiality

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### GCP 2.11

“The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).”

## DataFax and GCP 2.11

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- Each subject requires a unique ID number (DataFax key field)
- ID numbers are recorded with or without subject initials → this and other personal information cannot serve as key fields
- DFpdf (-b option) can blank out confidential data fields if data distribution via PDF is required

## 2. Subject & Data Confidentiality

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GCP 5.5.3 g\*

“Safe guard blinding, if any, (e.g., maintain the blinding during data entry and processing).”

## DataFax and GCP 5.5.3 g\*

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- Blinding during data entry requires being able to set plate-level permissions  
→ DataFax does not assist with this
- Internal SOPs need to be defined and followed
- Record as little personal identification information of subjects as possible

## 3. Safety Reporting

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### GCP 4.11

“All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (i.e., Investigator’s Brochure) identifies as not needing immediate reporting.”

## DataFax and GCP 4.11

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- Plate triggered procedures notify specified users when SAE plates arrive in the database
- Notification may be by:
  - fax
  - email
  - printed SAE plate

## 4. Quality Control

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### GCP 4.9.1

“The investigator should ensure the accuracy, completeness, legibility and timeliness of the data reported to the sponsor in the CRFs and in all required reports.”

## DataFax and GCP 4.9.1

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- Accuracy and completeness:
  - standard instructions for investigators completing DataFax CRFs
  - DataFax can accommodate/track an investigator certification CRF page

## DataFax and GCP 4.9.1 (cont'd)

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- Timeliness:
  - DF\_CTcrfs reports timeliness of data receipt, entry and time to 'clean'
  - visit map notifies data managers of missing/overdue data
  - plate triggered procedures may alert data managers to arrival of specified CRF pages

## 4. Quality Control

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### GCP 4.9.3

“Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections.”

## DataFax and GCP 4.9.3

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- Standard instructions for investigators making corrections to DataFax CRFs
- Investigators make corrections to the original source documents and refax
- DataFax recognizes refaxed CRFs
- All versions of a CRF page can be stored in the database (primary vs. secondary records)

## DataFax and GCP 4.9.3 (cont'd)

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- DataFax keeps an audit trail of database modifications and validation history of CRFs
- Unresolved and resolved QC notes are stored in the database and can be easily retrieved
- Include one or more hidden comment fields on every plate as a place to record investigator notes

## 4. Quality Control

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### GCP 5.1.3

“Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.”

## DataFax and GCP 5.1.3

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- Data management involves multi-level entry/review
- QC notes may be added at any stage of entry/review
- Edit checks help ensure data integrity
- ICR reduces data entry errors
- Double data entry (DDE) can be used as a quality assurance

## DataFax and GCP 5.1.3 (cont'd)

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- Visit map and edit checks automatically detect missing/overdue data
- DataFax includes study management reports
  - center/patient tracking
  - work flow
  - audit trail
- QC tool displays current status of the QC database

## 5. Records and Reports

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### GCP 5.21\*

“If a trial is terminated prematurely or suspended, the sponsor should promptly inform the investigators/institutions and the regulatory authorities of the termination or suspension and the reason for termination.”

### DataFax and GCP 5.21\*

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- QCmessages should be used to notify participating sites of trial termination or other issues
- Regulatory authorities must be informed by other means → QCmessages works only with those sites listed in the DataFax centers database

## 5. Records and Reports

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### GCP 5.22

“Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial study reports are prepared and provided to the regulatory authorities as required by the applicable regulatory requirements.”

## DataFax and GCP 5.22

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- DataFax programs can extract and manipulate data to aid in the preparation of study reports
  - DataFax Generic reports
  - DFexport.rpc
  - DFget
  - DFsas

## 6. Monitoring

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### GCP 5.5.4\*

“If data are transferred during processing, it should always be possible to compare the original data and observations with the processed data.”

## DataFax and GCP 5.5.4

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- DataFax shell level programs are used to manipulate but not change data
  - i.e. DFexport.rpc, DFsas, DFget, edit checks, DataFax generic reports
- No easy way to ensure that the latest version of the completed CRF at the site is the same as that in the database → DataFax does not assist

## Conclusion

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- Use GCP Guidelines as a basis for developing DataFax study SOPs → not all will be applicable
- Define a checklist that addresses issues in GCP Guidelines
  - which items are adhered to/assisted by your DataFax installation/study?
  - how are other items being handled?
  - checklist should become part of your software validation documentation