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# Documentation for DataFax Setup: Low Tech Tools for Data Managers

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## Why DataFax Setup Documentation?

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- Consistent and thorough documentation of DataFax study database setup requirements and testing needed to:
  - improve efficiency through standardization
  - enhance communication and organization
  - meet regulatory requirements for clinical studies with the potential for audit

## Some Background on SCHARP

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- The study team
- The CRF Development Process
- The role of the Data Operations Group in study setup

## Why Low Tech?

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- No access to programming/technical resources!
- Easy to create and maintain.
- Minimal training to use.
- Accessible to entire study team and well-supported.

## Creating the Tools

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1. Identify all the specific actions required to create a DataFax study database.
2. Diagram the flow or sequence of these actions.
3. Identify interdependencies.
4. Determine risk and appropriate validation method for each action using existing SOPs/WPGs.
5. Determine the number and types of tools needed based on typical workflow.

## Meeting Validation Needs

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- All documents are checked into a document management system.
- Most documents are maintained throughout the life of the study from setup to database lock.
- All documents are archived after database lock as part of the permanent study file.
- Put in context of SOPs/WPGs plus assessment of risk in regard to level of documentation.

## Tools

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- Study Setup Checklist and Timeline
- Plate/Variable Setup Checklist
- Visit Map Requirements
- Conditional Map Testing
- Edit Check Requirements and Testing

## Study Setup Checklist and Timeline

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- Serves as planning tool and overall timeline for completion of all tasks necessary for DataFax study database to be ready to receive data.
- Documents completion of various study database setup tasks including visit map, page map, centers database, edit checks, etc.

## Example of Study Setup Checklist and Timeline

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**Study Setup  
Checklist/Timeline  
Template**

## Plate/Variable Setup Checklist

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- Documents completion and verification of variable setup for each plate
- Provides helpful hints and reminders about conventions (WPGs provide more detail.)
- Serves as communication tool if setup is being completed by a team.
- Documents completion of modifications to plate setup after verification.

## Examples of Plate/variable Setup Checklist

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**Plate/Variable Setup  
Checklist Template**

**Example of Completed  
Plate/Variable Setup  
Checklist**

## Visit Map Requirements

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- Documents requirements for the visit map including all conditional maps prior to study start.
- Serves as checklist for completion and verification of visit map including all conditional maps.
- Serves as communication tool for the study team.

## Example of Visit Map Requirements

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**Visit Map Requirements  
Template**

**Example of Completed  
Visit Map Requirements**

## Conditional Map Testing

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- Documents testing of all conditional maps throughout life of study.

**Conditional Map Testing  
Template**

**Example of Completed  
Conditional Map Testing**

## Edit Check Requirements and Testing

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- Documents all edit check requirements prior to study start.
- Documents completion of testing for each edit check prior to study start
- Documents significant modification and addition of edit checks after study start.

**Edit Check Requirements  
and Testing Template**

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### Questions?

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