

Protocol ID: \_\_\_\_\_

Study Subject ID: \_\_\_\_\_

Study Name: \_\_\_\_\_

Interviewer

Site: \_\_\_\_\_

Name: \_\_\_\_\_

Event Name: \_\_\_\_\_

Interview Date: \_\_\_\_\_

Event Date: \_\_\_\_\_

## FRM046 DMP Prior to going live - v1.0

<b>Section Title: Page 1</b>
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Instructions:
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### User access

How will user access be recorded?  FRM052 Database Access  Other

Specify

### Data entry guidelines

What data entry guidelines will be provided to users?  Generic guidelines for data repository  
 Study specific guidelinesAre users required to enter test data?  Yes  No

Specify

### Data timeline

What has the data timeline been agreed to?  Instant (direct entry)  
 1 week after data is captured  
 2 weeks after data is captured  
 3+ weeks after data is captured

Provide reason for data entry timeline

### Blinding

Is the study blinded?  Yes  No

Specify who will be blinded and how this will be controlled

### Validations

Has a DVP been completed?  Yes  No

Explain choice

Validation methods

- Double entry  
 On entry validations  
 AECs

Type of UAT

- Fast track  Regular

Explain choice

How are data queries being handled?

- OpenClinica  Paper

Please explain why data queries are not being handled in OpenClinica

### Coding

Will any fields be coded?

- Yes  No

Coding plan (which terms will be coded, which dictionaries will be used)

Coding review (undertaken by and frequency)

### Reporting

How are AEs and SAEs being reported?

- OpenClinica  Paper

Please explain why AEs and SAEs are not being reported in OpenClinica

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**Section Title: Revision history**

Instructions:

<b>Revision date *</b>	<b>Revision notes *</b>	<b>Amendment type *</b>	<b>Authorised by</b>
		<input type="radio"/> (select) <input type="radio"/> Minor <input type="radio"/> Major	