

Protocol ID: \_\_\_\_\_  
 Study Name: \_\_\_\_\_  
 Site: \_\_\_\_\_  
 Event Name: \_\_\_\_\_  
 Event Date: \_\_\_\_\_

Study Subject ID: \_\_\_\_\_  
 Interviewer Name: \_\_\_\_\_  
 Interview Date: \_\_\_\_\_

**FRM046 DMP Prior to build start - v1.0**

**Section Title: Prior to build start p1**  
 Instructions:

Roles			
Role	Name	Start date	End date
<input type="radio"/> (select) <input type="radio"/> Data Management Lead <input type="radio"/> Chief Investigator <input type="radio"/> Principal Investigator <input type="radio"/> Clinical Data Lead			
<input type="radio"/> (select) <input type="radio"/> Data Management Lead <input type="radio"/> Chief Investigator <input type="radio"/> Principal Investigator <input type="radio"/> Clinical Data Lead			
<input type="radio"/> (select) <input type="radio"/> Data Management Lead <input type="radio"/> Chief Investigator <input type="radio"/> Principal Investigator <input type="radio"/> Clinical Data Lead			
<input type="radio"/> (select) <input type="radio"/> Data Management Lead <input type="radio"/> Chief Investigator <input type="radio"/> Principal Investigator <input type="radio"/> Clinical Data Lead			

**Study details**

Study P0 Number \*

Study name (short title) \*

Current protocol version

Current protocol version date

Is the study a CTIMP? \*  Yes  No

Is the study multisite? \*  Yes  No

**Data**

Data repository  OpenClinica  
 Formic  
 Excel  
 PostgreSQL  
 Other

If multiple options are selected,  
 explain choice

Specify

Data gathering method

- Paper CRFs followed by entry into data repository
- Direct entry into data repository
- Importing into data repository
- Other data (e.g. Lab data)

If multiple options are selected,  
explain choice

Specify

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

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

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

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

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

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

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

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

**Section Title: Prior to build start p2****Instructions:****Security**

Summarise how security is maintained (this refers to the measures that are used to block unauthorised access to data from outside the unit)

**Backups**

How will data backups be undertaken?

How frequently will data backups be undertaken?

Who will undertake backups?

**Audit trail**

How will an audit trail be recorded?

**Version control**

How will version control be undertaken?

**User access**

How will user access be controlled?

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

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

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

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

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

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

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

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

**Section Title: Version control**

Instructions:

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