**Contents List for Trial Master File**

1. Study Protocol [all versions with amendments (if any)]

2. Informed consent forms (all required languages), Translation and back translations with certificate

3. Case Report Forms

4. Investigator’s Brochure (if any)

5. Investigational product Information (if any)

6. IP accountability

7. Duty delegation log

8. CV,MRC , GCP certificates of all study team members

9. Investigator’s Undertaking

10.DCGI submission Acknowledgement (if applicable)

11.CTRI Details

12.IEC communication

13.SAE reporting details

14.Contracts and Agreements (if any)

15.Laboratory details (if any)

16.Other info as appropriate