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List of services provided by the Medical Statistics core facility:

**Scientific/methodological/statistical support**

- Competitive calls/grants
- Study design
- Peer review
- Manuscript presentation
- Consulting

**Study design and protocols**

- Meetings, teleconferences
- Sample size, statistical design
- Writing and reviewing statistical sections of protocol

**Electronic case report form (eCRF)&data management (DM)**

- Meetings for clinical trial initiation
- Documentation for initiation
- eCRFdefinition
- Data management plan (DMP)
- Data validation plan (specify checks)
- Database construction
- Annotated CRF
- Database validation
- Program and validate checks
- Training of investigators/monitors
- Access to investigators
- Importation of laboratory data
- Importation of electrocardiographdata
- Coding of data on adverse events
- Coding of medication data
- Coding of disease data
- Customised reports (recruitment, quality control, etc...)
- Individual patient unblinding module
- Customised screening data base and log module
- Data quality control
- Close database
- Final data management report
- Data base maintenance
- Closing of the project

**Reconciliation of severe adverse events**

- Listings + external manual checking
- Customised program

**Data transfer (DT) of statistical data**

- DT programming
- DT testing
- DT quality control

**Blind data review (BDR)**

- Meetings, teleconferences pre-DSMB
- BDRdeviation criteria preparation
- Preparation of BDR listings

## Medical Statistics core facility

### Plataforma d'Estadística Mèdica

183, Mallorca Street. Floor -1. Office #60. 08036 Barcelona

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BDR meeting  
BDR report  
Declaration of the different data subsets for analysis

#### **Statistical analysis plan (SAP)**

Meetings, teleconferences  
Provision of SAP with list of tables, listings and graphs

#### **Randomisation**

Preparation of randomisation codes  
Preparation of MACRO for randomisation

#### **Interim analysis**

Meetings, teleconferences  
Interim analysis of SAP  
Statistical programming  
Statistical analyses  
Statistical report/s

#### **Data monitoring committee (DMC)/Data and safety monitoring board (DSMB)**

Meetings, teleconferences  
Statistical analysis plan for DMC  
Statistical programming  
Statistical analyses  
Statistical report/s

#### **Statistical programming**

Statistical programs  
Documentation of statistical programs  
Validation of statistical programs  
Provision of final SAS datasets (electronic format)  
Provision of final SAS dataset documentation  
Emission of programming report

#### **Provision of datasets for CDISC/FDA**

Data transfer protocol  
Annotated CRF  
Statistical/DM Programming  
Quality control

#### **Results and statistical reports**

Meetings, teleconferences  
Statistical results (Summary Tables, TABLES; LISTINGS)  
Drawing up of draft and final statistical report  
Quality control of statistical report

## Medical Statistics core facility

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<http://www.idibaps.org/core-facilities/11/biostatistics-and-data-management>