APPENDIX A

THE 114 DIFFERENT ACTIVITIES CARRIED OUT BY DMS AND CRCS, COMBINED IN THEIR RESPECTIVE 24 MACRO AREAS

ARCHIVING

Paper archiving of clinical trials

Digital archiving of clinical trials

BIOLOGICAL SAMPLE PROCESSING

Sample processing

BRIEFING/PLANNING

Work planning

CLINICAL TRIAL FEASIBILITY/ EVALUATION PROCESS

Feasibility questionnaire

DATA MANAGEMENT/ DATA ENTRY

Medical history, examination, blood tests, concomitant therapies, vital parameters, eventi avversi e SAE

Questionnaires

Queries Resolution

Instrumental exams

eCRF/CRF DESIGN

Creation of eCRF/CRF

Revision/modificatio of eCRF

Creation/revision of hospital's database

EDUCATION/TRAINING

Journal Club

Shadowing courses

Training courses

Webinar

Training as speaker

Training as Listener

FUNDRAISING

Fundraising

GRANT

Scouting

Design calls

Submission calls

KPI'S REPORTING

Monitoring indicators (specify area)

MEETING

All the meetings

MULTICENTER CLINICAL STUDY COORDINATION

Coordination Centers (Multicenter Studies)

EVENT ORGANIZATION AND TRAINING

Master

Events

ECM courses

PUBLIC RELATION CRO/PHARMA

CRO and pharmaceutical company contacts

READING

bibliographic research

Journal club papers

SCOUTING

Scouting calls

STATISTICS

Statistical analysis

STUDY CLOSE OUT

Study close out

STUDY DESIGN

Designing/writing study protocols

STUDY DOC EVALUATION

Technical and scientific evaluation of interventional pharmacological studies - Profit Study

Technical and scientific evaluation of interventional no-pharmacological studies - Profit Study

Technical and scientific evaluation of interventional pharmacological studies – No Profit Study

Technical and scientific evaluation of interventional no-pharmacological studies – No Profit Study

Technical and scientific evaluation of observational pharmacological studies - Profit Study

Technical and scientific evaluation of observational no-pharmacological studies - Profit Study

Technical and scientific evaluation of observational pharmacological studies – No Profit Study

Technical and scientific evaluation of observational no-pharmacological studies – No Profit Study

Technical and scientific evaluation of interventional studies on medical device- Profit Study

Technical and scientific evaluation of observational studies on medical device- No Profit Study

Technical and scientific evaluation of interventional studies on medical device- No Profit Study

Technical and scientific evaluation of observational studies on medical device- Profit Study

Completeness check of documentation of interventional pharmacological studies - Profit Study

Completeness check of documentation of interventional no-pharmacological studies - Profit Study

Completeness check of documentation of interventional pharmacological studies – No Profit Study

Completeness check of documentation of interventional no-pharmacological studies – No Profit Study

Completeness check of documentation of observational pharmacological studies - Profit Study

Completeness check of documentation of observational no-pharmacological studies - Profit Study

Completeness check of documentation of observational pharmacological studies – No Profit Study

Completeness check of documentation of observational no-pharmacological studies – No Profit Study

Completeness check of documentation of interventional studies on medical device- Profit Study

Completeness check of documentation of observational studies on medical device- No Profit Study

Completeness check of documentation of interventional studies on medical device- No Profit Study

Completeness check of documentation of observational studies on medical device- Profit Study

Economic impact analysis of No-Profit Studies

Budget analysis of Profit studies

Center-specific documents

Center-specific documents of interventional pharmacological studies - Profit Study

Center-specific documents of interventional no-pharmacological studies - Profit Study

Center-specific documents of interventional pharmacological studies – No Profit Study

Center-specific documents of interventional no-pharmacological studies – No Profit Study

Center-specific documents ion of observational pharmacological studies - Profit Study

Center-specific documents of observational no-pharmacological studies - Profit Study

Center-specific documents of observational pharmacological studies – No Profit Study

Center-specific documents of observational no-pharmacological studies – No Profit Study

Center-specific documents of interventional studies on medical device- Profit Study

Center-specific documents of observational studies on medical device- No Profit Study

Center-specific documents of interventional studies on medical device- No Profit Study

Center-specific documents of observational studies on medical device- Profit Study

STUDY MANAGEMENT

Booking procedures or visits

Local sampling (serum/urine)

Preparation of kits for centralized samples

Evaluation of eligibility criteria

Informed Consent

Shipment of tissue samples

Courier booking/dry ice

Tablet questionnaires

Paper questionnaires

Creation papaer CRF

Resupply laboratory kit

Automatic drug resupply

Manual drug resupply

Upload images/video/instrumental procedures

Drug contabulity

Vital parameters (for multiple readings beyond the Day Hospital visit)

PK centralized samples

Drug/medical device management in IWRS (allocation, confirmation of arrival)

Refrigerator/freezer temperature collection

Ethic Committee Report

SAE

CRO communication management

Control procedures to be invoiced

Study-specific training

GCP Training

IATA Training

Medical records review

ISF management

Anonymization of reports

Drug disposal

Visits

STUDY MONITORING AND AUDIT

On site monitoring

Remote monitoring

START-UP PHASE

Documents collection (GCP, CV, Delegation Log, Training Log, ecc.)

SIV

WRITING

Paper

Abstract

Poster

Case Report

Working Paper of Public Health