How to organize a Clinical Theranostics Trial?

International Course on THERANOSTICS AND MOLECULAR RADIOTHERAPY

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October 4, 2017
**Sponsor:**
- Hospital
- Pharmaceutical company
- Biotech company
- National agency
- Academic institution

**Set-up phase**

**Conduct phase**

**Closure phase**

**SPONSOR**

**Participating sites:**
- Hospitals

**Patients inclusion and management**

**HOSPITAL**
Interventional
Retrospective
IMP
Prospective
Observational
Interventional
Retrospective
Prospective

Interventional

Observational

Retrospective

IMP/Device

Clinical trial
Set-up phase

Sponsor:
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Conduct phase

Last Patient Out
End of study

Results publication

SPONSOR

Patients inclusion and management

HOSPITAL

Participating sites:
Hospitals
Feasibility questionnaire / Survey

• Realistical number of potential patients?
• Participation in any competing trials?
• Facilities?
• Research physician/nurses?
• Imaging
  • Brand/model PET/CT?
  • Brand/model dose calibrator?
  • Routine QC procedure?
  • EARL accreditation?
• Radiopharmaceutical product(s)
  • Onsite production? GMP certification?
  • Commercial supplier?
Standard Procedures Imaging Manual - SPIM

- Equipment QC
  - Accreditation/Phantom program
- Data acquisition method
- Reconstruction
- Patients management (injection, positioning)
- Dosimetry method
- Data transfert
- Images QC

...
Protocol

Sites selection

Imaging

IMP supply chain
**IMP supply chain**

- Central production (e.g. commercial supplier)
  - Manufacturer
  - GMP compliance
  - Shipments to the sites

- Local production (e.g. on site)
  - Description of the manufacturing process
  - QC and Validation
  - Pre-clinical data
  - Labelling

→ Investigational Medical Product Dossier – IMPD
### Budget

- **Fix costs = Management Costs** (sponsor level)
- **Variable costs = per patient costs** (site level)

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>SCREENING</th>
<th>STUDY TREATMENT</th>
<th>EOS</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Cycle 1</td>
<td>Cycle X</td>
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<tr>
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<td>$C 1D 8$</td>
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<tr>
<td>Study coordination</td>
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<td>€0</td>
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<tr>
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<td>Pregnancy test (serum)</td>
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<tr>
<td>Drug infusion</td>
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<td>CT Scan</td>
<td>SOC</td>
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<tr>
<td>FDG PET/CT</td>
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</tbody>
</table>

**Total Costs:** €0

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**Notes:**
- Study coordination, Tracer Injection, Pregnancy test (serum), Drug infusion, Radio-pharmacist fees, CT Scan, FDG PET/CT
- Costs are listed for each cycle (Cycle 1, Cycle X, EOS)
- Costs are either €0 or one day clinic
Protocol

Synopsis

Sites selection

Imaging

IMP supply chain

Budget
Eligibility v1.0

CAM107

CRF Header Info

- Event: Registration Visit (06-Jul-2011)
- Sex: M
- Age At Enrollment: 32 Years - 7 Months - 20 Days
- Date of Birth: 14-Nov-1978

Study: Docetaxel in Patients With Completely Resected NSCLC
Site: Cambridge Center for Surgical Oncology

Discrepancy Notes on this CRF:
- New: 0
- Updated: 0
- Resolution Proposed: 0
- Closed: 0
- Not Applicable: 0

Inclusion Criteria:

All answers to questions 1-8 must be answered YES for subject to be eligible for participation.

1. Is the subject 18 years of age or older? [YES * ]
2. Does the subject have an ECOG status of 0-2? [YES * ]
3. Is the subject's WBC count 3,500/μL? [YES * ]
4. Is the subject's platelet count WBC count 100,000/μL? [YES * ]
5. Is the subject's serum creatinine <1.6 mg/dL? [YES * ]
6. Is the subject's serum bilirubin 1.6 mg/dL? [NO]
7. If the subject is of child-bearing potential, does the subject have a negative pregnancy test and agree to use adequate contraception during and two months after the duration of this study? [YES * ]
8. Has the patient been properly informed of the study and signed the Informed Consent? [YES * ]

Date Informed Consent was signed:

Save
Exit
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## Set-up phase

<table>
<thead>
<tr>
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<td>First Patient In</td>
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## Conduct phase

<table>
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<tbody>
<tr>
<td>End of study</td>
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## Closure phase

| Results publication |

## SPONSOR

## Participating sites:
- Hospitals

## Patients inclusion and management

## HOSPITAL
Medical & Safety review

Imaging quality

Monitoring

Patients accrual

Data management
Set-up phase
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Conduct phase

Closure phase
Last Patient Out
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SPONSOR

Patients inclusion and management

HOSPITAL

Participating sites: Hospitals

Competent Authorities and/or Ethics Committees approval
First Patient In
Main objectives

- Provide services and advice to the researchers
- Manage clinical trials from A to Z
Take home message

“Together, we are stronger”