Potential Roadblocks

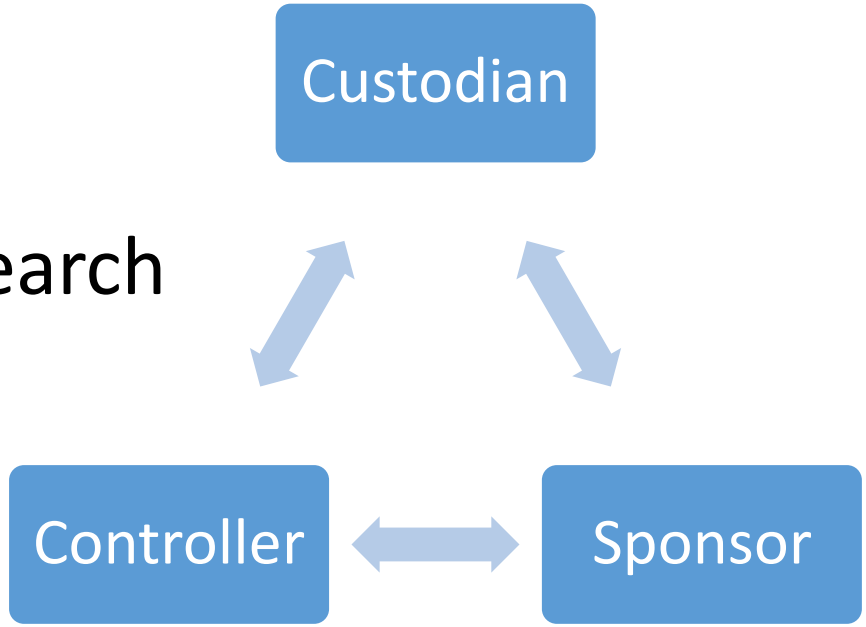
- Ethical
- Legal
- Logistic, operational and quality
- Professional and collaborative
- Financial

Ethical and approvals

- **Patient consent**
  - **Specific & explicit**
  - Extent of consent
  - Potential exemptions from consent
- **Ethical approval of research**
  - What is the “place of research” in international setting
  - Approval of specific research versus larger scoped approval
- **Other approvals**
  - Health authorities
  - Tissue authorities
  - Data protection authorities

Legal

- Owner
- Custodian
- Controller
- Sponsor of clinical research
  - Chain of custody



Logistical

- Paraffin block in an envelope by regular post: does it work in an international setting?

- What about packaging, labeling & transport?
  - Specialised transporters
  - Temperature control
  - Infectious diseases tests documentation
  - Traceability & tracking
  - Frequency of shipping

Professional and collaborative

GYNECOLOGIC CANCER INTERGROUP

An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

- Collaboration
- Co-operation – e.g. site won't give out sample
- Competition

"It is amazing how much we can accomplish when it doesn't matter who gets the credit."

Financial

GYNECOLOGIC CANCER INTERGROUP

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- Costs of taking samples
- Costs of transport
- Costs of storing samples and/or data
- Cost of management and governance

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SOLUTIONS

Ethics and consent

- One-time consent – broad yet not unlimited
- Tiered consent
- Article 32 of Declaration of Helsinki – potential exemption from consent
- Ethically defensible plan
- ‘Challenge decisions you don’t agree with!’
- Patient power

Logistics

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Two models for sample storage (and analysis)

Virtual biobanking

- Tissue remains in original site
- All testing carried out locally
- Requires robust assay protocols
- Easy from a regulatory perspective
- Useful for validation studies
- Not practical for rarer tumour types, small trials

Physical biobanking

- Tissue moved to a single/regional centre
- Testing carried out in a single laboratory
- Assay standardisation guaranteed
- Data does not need to move with tissue (and probably shouldn't)
- More difficult from regulatory perspective
- May generate unease regarding ownership/collaboration
- More expensive

Logistics and professional

Solutions 1 – MTAs and SLAs

MTA version 1.0 Dec 2014
Agreement for material transfer
from **PROVIDER** (*Site*) to **SPONSOR**

MATERIAL TRANSFER AGREEMENT

[*for interventional studies where site contracts are put in place anyhow, terms and conditions of a MTA shall be integrated in the main contract no separate MTA shall be made; parts in red italic or highlighted in yellow need adaptation to each specific case; other sections may need to be altered to fit specific national legislation*]

BETWEEN

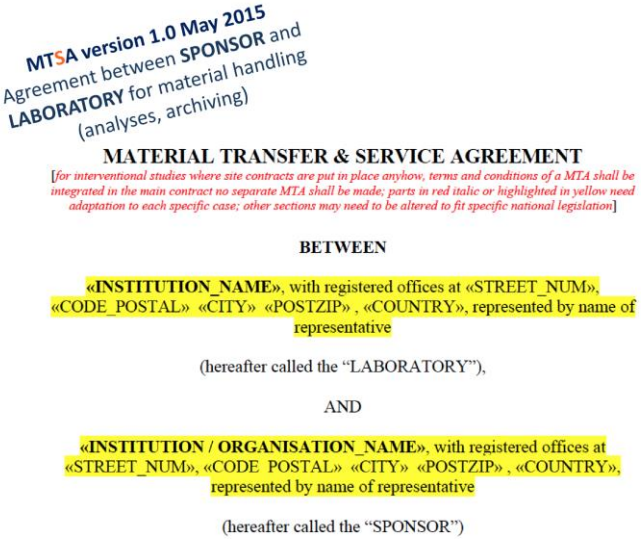
«INSTITUTION_NAME», with registered offices at «STREET_NUM», «CODE_POSTAL» «CITY» «POSTZIP» , «COUNTRY», represented by name of representative

(hereafter called the "PROVIDER"),

AND

«INSTITUTION / ORGANISATION_NAME», with registered offices at «STREET_NUM», «CODE_POSTAL» «CITY» «POSTZIP» , «COUNTRY», represented by name of representative

(hereafter called the "SPONSOR")



MTSA version 1.0 May 2015
Agreement between **SPONSOR** and
LABORATORY for material handling
(analyses, archiving)

MATERIAL TRANSFER & SERVICE AGREEMENT

[*for interventional studies where site contracts are put in place anyhow, terms and conditions of a MTA shall be integrated in the main contract no separate MTA shall be made; parts in red italic or highlighted in yellow need adaptation to each specific case; other sections may need to be altered to fit specific national legislation*]

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Logistics and professional

Solutions 2 – project-specific consortium development

- constitution based on recruitment to primary trial
  - Data sharing mechanism
  - Authorship policy
  - Regular 6 monthly face to face meetings
- formulation of research questions
- pilot tissue and data sets
  - 7 publications to date
  - 2 more in preparation
- establishing pathology/sample pipelines
  - Standardisation of protocols
  - Suitable for further trials eg STATEC

Financial

- Realistic sample size and estimated benefit
- Batching of transport
- National/regional centres
- Preferred vendors
- Real time vs retrospective
- Country-specific costings
- Publically available data
- Real-time reporting and tracking
- Patient organisations and fundraising