

# **An Industry Evaluation and Approval to Supply Tissue:**

## **A Case Study**

### **NHS Greater Glasgow & Clyde (GGC) Biorepository**

Jane Hair, Deputy Director GGC Biorepository

# Background

- NHSGGC Bio-repository: REC Approval support access to human tissue for both Academic and Industry researchers
- NHSGGC Bio-repository: HIS Accreditation
- Approach by Global Healthcare Company:  
Required there own assessment

# The Company

- Novo Nordisk
- “Novo Nordisk Way” : set of guiding principles which underpins every decision  
Policy ensuring best use of human tissue in a *“responsible ways, mindful of our duties”*
  - respect rights and wishes of donor*
  - meet applicable bioethics standards*
  - only collect when there is a real scientific need*
  - comply with relevant laws and regulations*
  - use human tissue of sufficient quality to be suitable for their research needs*

Opportunity for GGC Bio-repository

# The Evaluation Process: Stage 1:



Sourcing of human  
biosamples for use in Global  
Research

**Supplier self-assessment**

## Self Evaluation Form:

- 10 sections
- 77 questions

# The Evaluation Process:

## Stage 1:

### Self Evaluation Form:

- **Legal & Regulatory**
- **Ethical Review & Approval**
- **Donor Recruitment & Consent**
- **Documentation & Traceability**
- **Biosample Quality & Integrity**
  - Collection, Processing, Storage, QC, Selection & Release, Transport
- **Governance of Donor & Sample Data**
  - Confidentiality, Data, Data Security
- **Contracts, Agreements & Payments**
- **Document Management & Control:**
  - Documentation Requirement, Document Control, Documentation Review & Revision
- **Infrastructure:**
  - Staff, Facilities, H&S, Outsourcing

# The Evaluation Process:

## Stage 2:

### Site Visit:

- **Pre Visit: Send NHSGGC Bio-repository Document Library List.**  
Novo Nordisk highlighted documents to be available for review on the day of site visit.

# The Evaluation Process:

## Stage 2:

### Site Visit:

- Presentations
- Tour of GGC Bio-repository & Diagnostic Pathology
- Questions: arising from self evaluation form and tour
- Novo Nordisk alone: Time to review documents and discuss finding
- Closing feedback meeting: outcome of evaluation, conformity report & suggestions

# The Evaluation Process:

## Stage 3:

**Outcome:** Novo Nordisk Approval: No non-conformities & 5 suggestions

Lots of positive feedback:

- our openness to undergo evaluation
- obvious pride in our development and progress towards a Scottish research infrastructure
- strong approach to Legal aspects
- integration with Diagnostics
- ability to leverage samples for large populations
- supported our “front door” approach to patient consent
- our customised children and young adults PISs
- clear information on access by Industry in our PIS



# The Evaluation Process:

## Stage 3:

### Outcome:

- Novo Nordisk Observations & Suggestions Report: asked to respond and give proposed action plan
  - PIS could describe tissue used outside of UK
  - Laboratory area could be tidier
  - offer of Laboratory coats
  - comment on controlled access on the day of visit
- Novo Nordisk accepted NHSGGC Bio-repository action plan



***Five Star Tissue Supplier Rating***

**Confidence our HIS Standards supported  
Industry evaluation**