BiologicallyDerivedProduct FHIR Resource Proposal

- **BiologicallyDerivedProduct**
- **Owning committee name**
- **Committee Approval Date:**
  - October 5, 2017
- **Contributing or Reviewing Work Groups**
  - Patient Care
  - Pharmacy
- **FHIR Resource Development Project Insight ID**
  - 1128 Patient Care FHIR resource review
- **Scope of coverage**
  - A material substance originating from a biological entity intended to be transplanted or infused into another (possibly the same) biological entity.
  - Examples include:
    - hematopoietic stem cells (bone marrow, peripheral blood, or cord blood extraction)
    - blood (whole, extracted cells, plasma, etc)
    - organs
    - tissues (porcine valves, skin, bovine cardiac tissue, etc.)
    - manipulated cells (e.g. CAR T-cells)
  - The workflow using this resource (e.g., request, administration) should be discussed and implemented in a consistent way as other similar resources are handled (e.g., device, medication)
- **RIM scope**
  - No identified mappings to RIM 2.46 objects.
- **Resource appropriateness**
Organs, tissues, and fluids obtained from one biological entity (person or animal) for the purpose of infusion, transplantation or grafting to another biological entity are neither Specimens ("used for diagnostic and environmental testing") nor Devices ("an instance or a type of a manufactured item") nor Medications (drug, ingredients, and packaging) nor Substances ("homogeneous material with a definite composition"). Furthermore, there is established a relationship between two entities, the donor and the recipient.

Expected implementations [edit | edit source]

This will be used in reporting clinical outcomes to the Center for International Blood and Marrow Transplant Research (CIBMTR) after hematopoietic cell transplant (bone marrow, peripheral blood stem cells, cord blood).

This resource is not used in CCDA.

Content sources [edit | edit source]

For reporting of clinical outcomes to CIBMTR, source data would come from federated systems at the transplant center, e.g., from the EHR, transplant databases, labs

- Patient undergoes hematopoietic cell transplantation (HCT) using autologous BiologicallyDerivedProduct
- Patient undergoes HCT using HLA-matched BiologicallyDerivedProduct from another person
- Patient receives post-HCT infusion of donor t-cells (BiologicallyDerivedProduct)
- Patient receives blood (BiologicallyDerivedProduct) transfusion
- Patient receives HLA-matched platelets (BiologicallyDerivedProduct)
- Patient receives heart (BiologicallyDerivedProduct) transplant from deceased donor Patient
- Patient donates kidney (BiologicallyDerivedProduct) for transplantation in another Patient
- Patient received pig heart valve (BiologicallyDerivedProduct)

Resource Relationships [edit | edit source]

ProcedureRequest (for collection)

Patient ("receiver" and "source")

Practitioner (who collected product)

Substance (product processing)

DiagnosticReport (containing HLA-typing)

BiologicallyDerivedProduct ("parent" product for multi-day collections)

Procedure (one for collection and one for transplantation, will need to add BiologicallyDerivedProduct to the "usedReference")

Timelines [edit | edit source]

ready by Jan 2018 connectathon

?? voting

gForge Users [edit | edit source]

When Resource Proposal Is Complete [edit | edit source]

When you have completed your proposal, please send an email to FMGcontact@HL7.org

FMG Notes