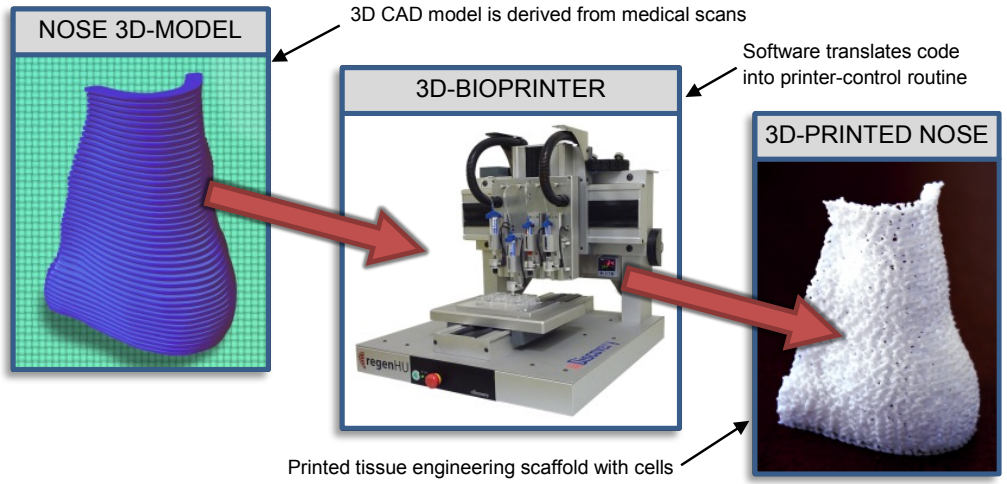
3D Bioprinting: Commercialising Personalised ATMP/Device Combination Products



RiHN Feasibility study launch event, Loughborough University, 19/11/2015

Andy Gleadall

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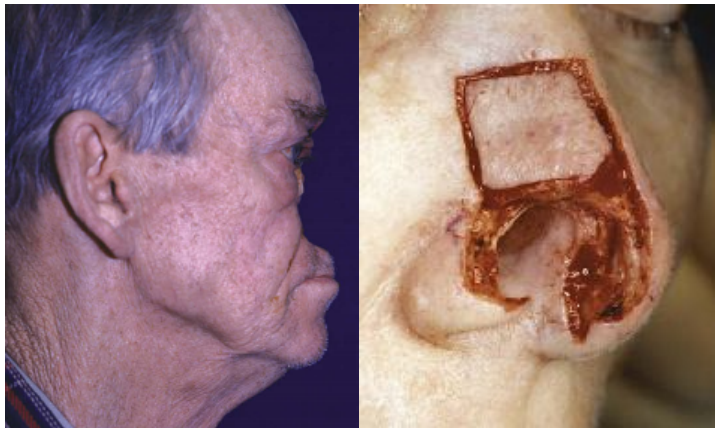
BACKGROUND

- Why replacement noses?
  - Carcinomas
  - Trauma
  - Substance abuse, infections, etc.
- Why bioprinting?
  - Customisable
  - Potentially better patient outcome
- Bioprinting technology:
  - Ideal candidate for RDM
  - Not within the current regulatory framework
- Previous project: Challenge-Led Regenerative Medicine Manufacturing Research



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AIM AND OBJECTIVES

- Aim:
  - To identify the possible modes of operating a commercial-scale distributed business for bioprinting implants containing living cells

- Objectives – identify the following:
  - Technical, economic and regulatory constraints
  - More appropriate regulatory framework options
  - Alternative methods for RDM
  - Required research areas

Benefits and impacts identified

- Benefits of bioprinting:
  - Save surgery time
    - Implications on cost, patient outcome, number of operations, etc.
  - Better patient outcome
    - Nose reconstruction fidelity, potentially improved functionality, surgical success rate, etc.

- Benefit of RDM
  - Determine this during the project
  - Why not use a centralised approach?
    - E.g. less transport of cells / tissue

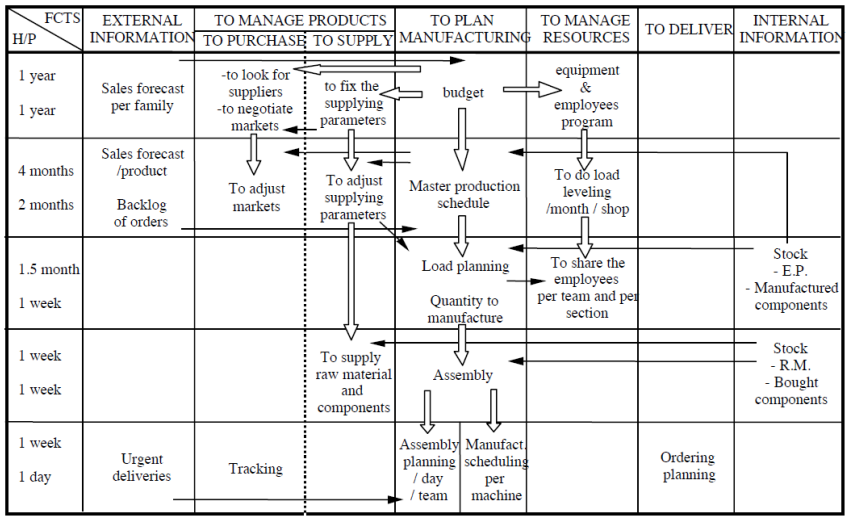
NOVELTY

- Little existing work on:
  - Challenges of applying regulatory framework -

    Impact on:
    - Product /patient
    - Bioprinting feasibility
    - RDM feasibility
  - Are there potential adaptations to the regulatory framework?

APPROACH

- Risk analysis for RDM bioprinting
- Interview, visits to clinics, workshops
- Model RDM bioprinting (GRAI Grid, IDEF0);



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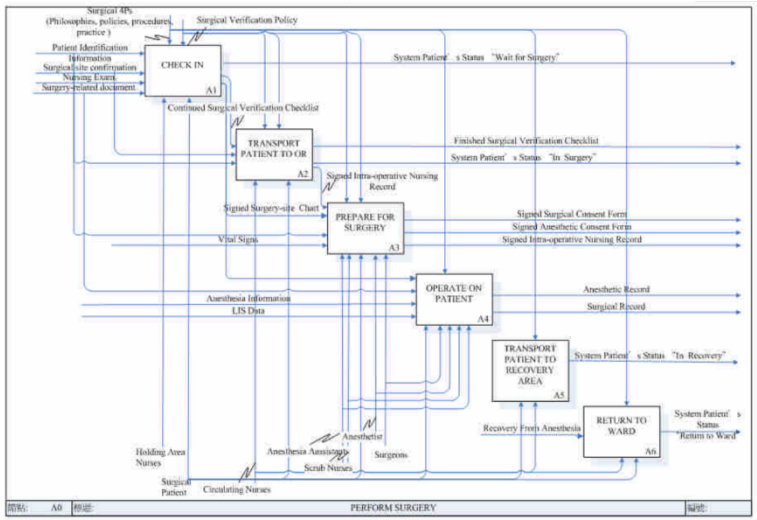

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OUTPUTS

- Gap analysis and future status of combination products
- Framework for future operational business models
- Publication and dissemination of results

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  - Andy Gleadall – University of Nottingham
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  - Nick Medcalf – Loughborough University
  - Paul Hourd – Loughborough University

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  - Challenge-Led Regenerative Medicine Manufacturing Research:
    - Jing Yang, Laura Ruiz-Cantu, Kevin Shakesheff – University of Nottingham
    - Callum Faris - Queens Medical Centre, Nottingham University Hospital

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