BioMod Interview schedule template: cell and gene therapy logistics companies

1) **Preliminary discussion**

* Brief introduction to aims and objectives of ESRC Biomodifying Technologies project
* Interviewee rights: confidentiality, anonymity and right to withdraw
* Data management plan – interview transcripts with identifying data removed will be deposited in UK Data Archive at end of project
* Opportunity to ask questions about project
* CONSENT FORM -digital

2) **Interviewee and team overview**

* Can you tell me a bit about your professional background?
  + What qualifications do you hold?
  + Do you have any scientific training?
  + If so in what discipline(s)?
  + Have you previously held any academic positions?
  + Or worked for other RM firms?
* Can you expand a bit on your current role as [title of role redacted] for cell and gene therapy with the company?

3) **Company**

* Can you say a bit about the product or services you provide? How novel is it compared to existing tools/products?
  + How standardised is your service and can it be customised for particular types of therapy, especially where a patient’s own cells are modified as with CAR-T therapies?
  + Is there competition from open source or ‘in house’ software for e.g. [name of product]?
* Roughly how long has your company been developing this technology and how many people are employed by the company?
* Your website emphasises your global reach –would you say the main business areas are, USA, European, Japan, China?
* Are these the biggest markets for cell and gene therapies?

4) **Current scientific work**

* What do you see as the main challenges for the development of cell and gene therapies with regards to supply chain management and logistics
  + What are the advantages of digitally managing tasks that would previously have been done manually?
  + Are there any drawbacks -e.g. loss of skills?
  + Are there limits to what can be standardised, or at what level of detail and where does this matter?
  + Are there circumstances where some measure of flexibility or operator judgement needs to remain?
  + Are there particular challenges of the clinical trials setting & the support you provide in this regard?
  + E.g. Novel trial designs?
  + Do your logistics support services extend to other critical quality attributes of cell and gene therapy products besides temperature and shelf life?
  + Do you ever help to define CQAs [critical quality attributes]?
* Have you provided services to groups (academic or commercial) working with our case study technologies of induced pluripotent stem cells or genome editing? (NB we do not need details of clients)
  + If so, are they a large part of your client base or not?
* Do or might induced pluripotent stem cell-based cell therapies or clinical applications of gene editing tools like CRISPR or zinc finger mega-nucleases pose any particular challenges in terms of the services you provide?
* Is there anything special about them in terms of logistics, or supply chain management?
* Have you had any experience in relation to clients working with 3D printed cell constructs?

5) **Network and resources**

* Do you or have you had involvement with any of the following:
  + UK Advanced Therapy Treatment Centres?
  + Cell and Gene Therapy catapult?
  + collaborative activities with other institutions (universities, other firms, Contract Research Organisations, big pharma, NHS or private hospitals)?
* If so could you provide some detail on how this relationship works?
* In your experience, do your timeframes for working align with the groups you are contracted with or do you find that they either need things faster than your processes, or are a lot slower, maybe with long periods of inactivity, than you would prefer?
* Why / when do you collaborate with or outsource tasks to these groups?

6) **Regulation and translation**

* How, if at all, does regulation impact your work?
* Are there any specific intellectual property issues?
  + What are the main forms of IP involved e.g. patents, copyright, trade secrets?
  + Is one of these more important than the others?
  + Do you find you have to license in material from other companies or universities?
  + Do you out-license any aspects of your IP portfolio to other groups?
  + How is your software protected?
  + Who owns the data that your software uses?
* Are there any data protection or privacy issues?
* [question redacted as it is specific to this company’s business model]
* Do you find the regulatory climate difficult to navigate?

7) **Perspective and future of the field**

* How do you see the UK’s position in relation to the wider global work on regenerative medicines, and related therapies like CAR-T?
* What do you envisage for future development of cell and gene therapies?