



TYPE 1
DIABETES
**GRAND
CHALLENGE**

Funding call: Stem Cell Derived Beta Cell Product Validation Sites – Frequently Asked Questions

Q1: How will the cells be shipped?

Shipping will be via a dedicated courier system with experience in shipping live cells internationally. Within studies done in the US, cells were shipped in culture media at 4°C within 24-hours but then were stored in the same conditions for up to two-days before use.

ARMI anticipate that shipping from the US to the UK will take 48-72-hours falling within this window. But they will also run some internal mock ships to examine cell viability.

The cells will be shipped in test tubes.

Q2: Will both be shipped at the same time or is the plan for them to be sent separately? If the latter, what is the likely delay between shipments?

The 2 different products will be shipped separately. The overlap is currently unclear and open to negotiation with the different test labs based upon their availability and desired workflow. However, a consensus will be necessary between all test labs as each will receive from the same batch per product.

Q3: How many cells will each site receive, and will these be from the same batch?

Each of the three sites will receive 100M cells from the same batch per product.

Please remember that there are two different cell products that will be tested.

Q4: Are the cells received as clusters?

Yes, the cells will be received as small clusters.

The no. of cells per cluster will not be defined as they aggregate naturally. Sites are welcome to disaggregate the clusters and reassemble to a set cell number.

Q5: Where there any changes in the functionality of the cells post shipping?

At the three US test sites the functionality of the cells was found to be moderately reduced in culture post shipping.

However, this was not observed in vivo with cell functionality retained.

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Q6: Is their flexibility with the protocols?

Yes, there will be a baseline protocol and certain measurements will need to be taken. For example, for the *in vivo* studies all sites will be required to measure blood glucose and weight and to monitor C-peptide throughout the study.

However, there may be variations between the sites, and this is viewed as a strength.

Q7: We can only undertake one aspect of the experiments (e.g *in vitro*), is it possible to apply and only address one aspect of the call?

We are unable to accept applications that only focus on the *in vitro* or the *in vivo* aspects of the validation study. However, we encourage you to collaborate with other applicants, so not to lose the vital experience you bring in a specific area.