**FRM075 Trial Specific Risk assessment for Direct to Patient supply of trial medicines**

**Protocol:\_\_\_\_ PI:\_\_\_\_\_\_\_\_\_\_\_\_\_P0xxxxx /CRFxxxxx**

|  |  |
| --- | --- |
| ***IMP Information*** |  |
| *Name of Product (s) to be delivered including ancillaries* |  |
| *Is the IMP considered to be hazardous in any way* |  |
| *Is the IMP a Controlled Drug* |  |
| *Formulation and primary packaging* |  |
| *Size and weight of package (approx.)* |  |
| ***Storage/ transit considerations*** |
| *Usual storage conditions* |  |
| *Product stability data (if available)* |  |
| *Max transit time uncontrolled* |  |
| *Max transit time controlled* |  |
| *Is transit temperature monitoring required?* |  |
| *What insurance is required if any?* |  |
| *Impact of delayed posting on product integrity* |  |
| *Impact of delayed posting on subject (missed dosing)*  |  |
| ***Patient group considerations*** |
| *How will patients give consent for this*  |  |
| *What education is required i.e. drug receipt, storage and administration* |  |
| *How will this be provided* |  |
| *Will patients need support at home to manage this* |  |
| *How will patients confirm receipt* |  |
|  |  |
| ***Staff considerations; who has responsibility for the following:*** |
| *Taking consent and up to date address* |  |
| *Booking appointments* |  |
| *How will prescriptions be sent to pharmacy – will they be done in advance of scheduled visit or on the day?* |  |
| *Who will book the courier if required?* |  |
| *Will a same day service be required – can it be booked in advance?* |  |
| *Who will receive confirmation of receipt at site* |  |

**Use the above assessment to decide on the most appropriate process for IMP delivery for this**

|  |
| --- |
| **General** |
| Can the IMP be safely delivered | Yes / No |
| Is the patient group able to receive and store IMP safely? |  |
| How will the patient be trained to administer IMP? |  |
| Chosen delivery service |  |
| Costs and payments |  |
| **Transit details** |
| Method of delivery |  |
| Name of Courier (if applicable) |  |
| Controlled or uncontrolled packaging? Who is providing, how is controlled packaging validated |  |
| Size of shipper required |  |
| Method of booking and who is responsible for booking (include details on how to book) |  |
| Method of confirming receipt  |  |
| If temperature monitoring is required how is this reported to site and sponsor |  |
| Who is responsible for packaging the IMP? |  |
| Final Approvals |
| Process approved by PI / CPM & Sponsor (attach evidence e.g. email) |  |
| Process approved by Pharmacy |  |
| Date |  |
|  |  |
|  |  |
|  |  |