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| **Assessment tool for drug products used in clinical trials (Papworth Sponsored)** | | | | | | | | | | | | | | | | | | |
| **TRIAL:** | |  |  |  |  | | | | | | | **PI:** | | | | | | | |
| Product name and form: | |  | | | | | | | | | | | | Date |  | | | |
| Brand Name: | |  | | | | | | | | | | | | Completed by: | | | | |
| Strength: | |  | | | | | | | | | | | |  | | | | |
| Manufacturer: | |  | | | | | | | | | | | | | | | | |
| Proposed indication /use within trial (Inc. route of administration) | |  | | | | | | | | | | | | | | | | |
| Product type (provide further details below) | | ATMP Genetically modified Monoclonal Antibody RNA molecule Peptide Chemical | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| Product classification | | Medicinal Licensed Medicinal Unlicensed Non-medicinal | | | | | | | | | | | | | | | | |
| Expected MHRA Risk Category | | A B C | | | | | | | | | | | | | | | | |
| A full in use risk assessment must also be undertaken by the pharmacist specific to the type of product - this assessment will cover risks associated with IMP handling and administration, prescribing and | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| **Supply** | | | | | | | | | | | | | | | | | | |
| Where is product supplied from? | Sourced by Pharmacy | | |  | | | | | | | Expected drug cost £ | | | | | | | |
| Sourced by Investigator | | |  | | | | | | |
| Provided by Industry | | | Commercial Stock | | | | | Trial specific stock | |
| 1. **Licensing and manufacture** | | | | | | | | | | | | | | | | | | |
| A1. Does the product have a UK marketing authorisation | | | | | | | Yes | | Answer A2.1 | | | | | | | | | |
| No | |  | | | | | | | | | |
| A2. Does the product have a marketing authorisation elsewhere in the EU / EEA? | | | | | | | Yes | |  | | | | | | | | | |
| No | | If not where is it used: | | | | | | | | | |
| A2.1 Will it be used within the marketing authorisation? | | | | | | | Yes | |  | | | | | | |  |  |  |
| No | |  | | | | | | |  |  |  |
| A3. Where is the product manufactured and what assurance of pharmaceutical quality is available? Manufacture license, EU GMP equivalence statement etc. NB all medicines must be of pharmaceutical grade quality suitable for use in humans. Attach all relevant documents | Details of manufacturer e.g. expertise in area, | | | | | | | |  | | | | | | | | | |
| Licences held (evidence of MIA(IMP) | | | | | | | |  | | | | | | | | | |
| QP declaration available (if required) | | | | | | | | Yes / No | | | | | | | | | |
| Third party required to import IMP? | | | | | | | | Yes / no | | | | | | | | | |
| Third party required to provide QP certification: | | | | | | | | Yes / no | | | | | | | | | |
| A4. What evidence is there to support the use of this medication for the trial indication (Attach IB or any relevant published articles) | | | | | | | | | | | | | | | | | | |
| 1. **Manufacture, Assembly and Labelling requirements** | | | | | | | | | | | | | | | | | | |
| B1. Does the IMP require any manufacturing processes prior to use in trial i.e. over encapsulation, re-formulation, blinding | | | | | | yes | | no | | If yes then the services of a third party must be sought | | | | | | | | |
| B2. Dispensing from bulk in to individual packs or batches | | | | | | yes | | no | | If yes can be done under exemption if not blinded | | | | | | | | |
| B3. Labelling requirements (annex 13 compliant) | | | | | | None (type A only) | | | | Reduced (type A and B) | | | Full (Type B and C) | | | | | |
| Labelling to be carried out by manufacturer or 3rd party | | | | | | yes | | no | |  | | | | | | | | |
| Labelling to be carried out under exemption | | | | | | yes | | no | |  | | | | | | | | |
| What quantity of IMP is required and over what time period? | | | | | |  | |  | |  | | | | | | | | |
| 1. **Storage and Safety** | | | | | | | | | | | | | | | | | | |
| C1. Is the product provided in a suitable container | | | | | | yes | | no | | Details: | | | | | | | | |
| C2. Storage requirements and expected storage location. Refer to published stability data. | | | | | |  | | | | | | | | | | | | |
| C3. What level of temperature monitoring is expected | | | | | |  | | | | | | | | | | | | |
| C4. What are the storage requirements during transport? | | | | | |  | | | | | | | | | | | | |
| C5. Expected volume of IMP to be stored at each site | | | | | |  | | | | | | | | | | | | |  | |  |
| C6. Can it be stored appropriately i.e. securely on site? | | | | | |  | | | | | | | | | | | | |
| C7. IS there any risk should a spillage occur? | | | | | |  | | | | | | | | | | | | |
| C8. Is any PPE required for handling the packaged product? | | | | | |  | | | | | | | | | | | | |
| C9. How will the product need to be transported around the site(s) | | | | | |  | | | | | | | | | | | | |
| C10. Considerations for waste product (used and unused containers) | | | | | |  | | | | | | | | | | | | |

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| 1. **Supply Chain, Transport and Destruction** | | | | | |
| D1. Is the product readily available from a recognised supplier | | yes | no | Please state who: | |
| D1.1. Details of the proposed supply chain. NB Papworth need to use the services of a 3rd party importer for medicines. Who will be responsible for ordering | |  | | | |
| D2. Can the product be delivered without affecting its quality? | | yes | no |  | |
| D3. What is the expected lead time for product delivery | |  | | | |
| D4. Risks associated with receiving and handling packaged IMP | | yes | no |  | |
| D5. Are there any foreseen risks with transporting the IMP on site? What actions need to be taken in case of spillage? | | Yes | no |  | |
| D6. Are there any specific disposal requirements for the product | | yes | no |  | |
| D6.1 If yes please explain and state what arrangements have been made | |  | | | |
| D5. How will the product be purchased? Via investigator accounts, via pharmacy for investigator billing, via pharmacy – NHS funding | |  | | | |
| D6. Will the product be entered onto JAC or dispensed via the trials room (paper logs only) | |  | | | |
| D7. Is the trial multisite? How will IMP be delivered to external sites | | yes | no |  | |
| **Summary & Outcome** | | | | | |
| Is this product considered to be of a suitable standard for human use? | | yes | no |  | |
| Is this product available from an authorised manufacturer? | | yes | no |  | |
| Is this product sourced via an appropriate supplier | | yes | no |  | |
| Can the product be stored appropriately and securely on site? | | yes | no |  | |
| Will Pharmacy be required to assemble or label under the exemption | | yes | no |  | |
| Will any work need to be contracted out to a 3rd party | | yes | no |  | |
| |  | | --- | | Any other comments, recommendations or outcomes of the assessment can be made here: | | | | | | |
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|  | | | | | |
| Assessed by: |  | Lead Pharmacist for Clinical Trials | | | Date: |
| Authorised by: |  | Chief investigator | | | Date: |