**CLINICAL TRIAL BY USING STEM CELLS AUTHORIZATION APPLICATION FORM**

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| **THIS SECTION IS FOR NHRA USE ONLY** | | |
| Date of Receipt:  Date of Triage : | Date of request for additional information: | Rejection :  Date of Rejection: |
| Date of valid application:  Type of CTC review: | Date of receipt of additional / amended information: | Authorisation/ positive opinion:  Give date: |
| NHRA CTA Number:  ICTR/ITN Number:  Date of Verification of ICTR/ITN: | | Withdrawal of application  Date of Withdrawal: |

##### **Instructions:**

Use this form for each application requesting an authorization/no objection to conduct a **new** clinical trial/research study. Fill out this form **electronically** as appropriate and provide an original duly signed print out.

Check all the boxes that apply to your particular Clinical Trial. Use N/A when not applicable. **Unanswered sections will be considered as Incomplete Submission.**

A**pplications will not be submitted for review by NHRA’s Clinical Trial Committee until the submission package content validation is completed within 10 days**. Sponsors-Applicants-CROs must ensure that all documents are in final versions[[1]](#footnote-1), and signed by all relevant parties.

##### **STUDY IDENTIFICATION**

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| --- | --- | --- | --- |
| **A.1** | **Full title of the study:** | | |
|  | | | |
| **A.2** | **Study protocol number:** | | |
|  | | | |
| **A.3** | **Is there any study registry identifiers? (e.g. EudraCT number, US NCT number)** | Yes | No |
| **A.3.1** | **If yes, please specify:** |  |  |
|  |  |  |  |
| **A.4** | **Is the study currently being conducted or planned to be conducted in any other country?** | Yes | No |
| **A.4.1** | If yes, please list the name of countries: | | |
|  |  | | |
| **A.5** | **Is there any other country where the study has been approved?** | Yes | No |
| **A.5.1** | If yes, please list the name of countries: | | |
|  | | | |
| **A.6** | **Does the study involve pediatric population?** | Yes | No |

##### **INVESTIGATORS AND SPONSOR-APPLICANT IDENTIFICATION**

|  |  |  |  |  |
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| **B.1** | **Principal Investigator** | | | |
| **B.1.1** | Name and surname: | | | |
| **B.1.2** | Institution: | | | |
| **B.1.3** | Address: | | | |
| **B.1.4** | Phone number: | | | |
| **B.1.5** | E-mail address: | | | |
|  | | | | |
| **B.1** | **Co- Investigator** | | | |
| **B.1.1** | Name and surname: | | | |
| **B.1.2** | Institution: | | | |
| **B.1.3** | Address: | | | |
| **B.1.4** | Phone number: | | | |
| **B.1.5** | E-mail address: | | | |
|  | | | | |
| **B.2** | **Sponsor** | | | N/A |
| **B.2.1** | Name of the sponsor: | | | |
| **B.2.2** | Status of the sponsor: | Commercial | Non-commercial | |
| **B.2.3** | Name and surname of the contact person: | | | |
| **B.2.4** | Title of the contact person: | | | |
| **B.2.5** | Address: | | | |
| **B.2.6** | Phone number: | | | |
| **B.2.7** | E-mail address: | | | |
|  | | | | |
| **B.3** | **Legal Representative of the Sponsor or Contract Research Organization in Bahrain for the Purpose of This Study** (repeat as necessary) | | | N/A |
| **B.3.1** | Name of the organisation: | | | |
| **B.3.2** | Name and surname of the contact person: | | | |
|  | Title of the contact person: | | | |
| **B.3.3** | Address: | | | |
| **B.3.4** | Phone number: | | | |
| **B.3.5** | E-mail address: | | | |

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| **B.4** | **APPLICANT** | | |
| **B.4.1** | **Is the Applicant the Sponsor?** | Yes | No |
| **B.4.2** | **Is the Applicant the Sponsor’s Legal Representative?** | Yes | No |
| **B.4.3** | **Is the Applicant a Registered CRO?** | Yes | No |
| **B.4.4** | Name of the person completing the Applicantion: | | |
| **B.4.5** | Name of the Organization: | | |
| **B.4.6** | Title of the personcompleting the Application: | | |
| **B.4.7** | Address: | | |
| **B.4.8** | Phone number: | | |
| **B.4.9** | E-mail address: | | |

1. **INFORMATION ON EACH INVESTIGATIONAL PRODUCT (IP)**

*Information on each ‘bulk product’ before study-specific operations (blinding, study specific packaging and labelling) should be provided in this section for each IP being tested including each comparator and each placebo, if applicable. If the study is performed with several products use extra pages and give each product a sequential number. If the product is a combination, product information should be given for each active substance.*

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| --- | --- | --- |
| **C.1** | **IP Identification**  Indicate which of the following is described below, then repeat as necessary for each of the numbered IPs to be used in the study (assign numbers from 1-n): | |
| **C.1.1** | This refers to the IP number: | |
| **C.1.2** | IP being tested | IP used as comperator (placebo) |

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| --- | --- | --- | --- |
| **C.2** | **Status of IP** | | |
| **C.2.1** | Does this IP to be used in the study have a marketing authorisation in Bahrain? | Yes | No |
| **C.2.1.1** | If yes, please specify; | | |
| **C.2.1.2** | Trade name: | | |
| **C.2.1.3** | Name of the marketing authorisation holder: | | |
| **C.2.1.4** | Marketing authorisation number: | | |
| **C.2.1.5** | List of other countries granted marketing authorization for the same product: | | |
| **C.2.1.6** | Is the IP modified in relation to its Marketing Authorisation? | Yes | No |
| **C.2.1.6.1** | If yes, please specify; | | |
| **C.2.2** | Has the use of the IP been previously authorised in a clinical study conducted by the sponsor in any other country? | Yes | No |
| **C.2.2.1** | If yes, please specify countries: | | |
| **C.2.3** | Has the IMP been designated in this indication as an orphan drug? | Yes | No |
| **C.2.3.1** | If yes, give the orphan drug designation number : | | |

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| **C.3** | **Description of the IP** | | |
| **C.3.1** | Product name (if applicable): | | |
| **C.3.2** | Product code (if applicable): | | |
| **C.3.3** | Pharmaceutical form (use standard terms): | | |
| **C.3.4** | Is this a specific paediatric formulation? | Yes | No |
| **C.3.5** | Maximum duration of treatment of a subject according to the protocol: | | |
| **C.3.6** | Dose allowed: | | |
| **C.3.7** | First dose for first-in-human clinical trial (specify; per day or total dose; units and route of administration): | | |
| **C.3.8** | Maximum dose allowed (specify; per day or total dose; units and route of administration): | | |
| **C.3.9** | Route of administration (use standard terms): | | |
| **C.3.10** | Name of each active substance : | | |
| **C.3.11** | Full molecular formula: | | |
| **C.3.12** | Chemical/biological description of the Active Substance: | | |
| **C.3.13** | Strength (specify all strengths to be used): | | |
| **C.3.14** | Concentration unit: | | |
| **C.3.15** | Concentration type (“exact number”, “range", "more than” or “up to”): | | |
| **C.3.16** | Concentration (number): | | |

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| **C.4** | **Type of IP** | | | | |
| **C.4.1** | Does the IP contain an active substance of | chemical origin? | biological/biotechnological origin? | | |
| **C.4.2** | Is this a: | | | | |
| **C.4.2.1** | Advanced Therapy IP (ATIP)? | | | Yes | No |
| **C.4.2.2** | Somatic cell therapy medicinal product**[[2]](#footnote-2)**? | | | Yes | No |
| **C.4.2.3** | Gene therapy medicinal product? | | | Yes | No |
| **C.4.2.4** | Tissue Engineered Product? | | | Yes | No |
| **C.4.2.5** | Combination ATIP (i.e. one involving a medical device)? | | | Yes | No |
| **C.4.2.6** | Combination product that includes a device , but does not involve an Advanced Therapy? | | | Yes | No |
| **C.4.2.7** | Radiopharmaceutical medicinal product? | | | Yes | No |
| **C.4.2.8** | Immunological medicinal product (such as vaccine, allergen, immune serum)? | | | Yes | No |
| **C.4.2.9** | Plasma derived medicinal product? | | | Yes | No |
| **C.4.2.10** | Extractive medicinal product? | | | Yes | No |
| **C.4.2.11** | Recombinant medicinal product? | | | Yes | No |
| **C.4.2.12** | Product contain genetically modified organism? | | | Yes | No |
| **C.4.2.12.1** | If yes, authorisation for contained use or release :  has been granted  pending | | | | |
| **C.4.2.13** | Herbal medicinal product? | | | Yes | No |
| **C.4.2.14** | Homeopathic medicinal product? | | | Yes | No |
| **C.4.2.15** | Other: | | | Yes | No |
| **C.4.2.15.1** | If yes, please specify including mode of action. | | | | |
| **C.4.3** | Is it an IP to be used in a first-in-human clinical trial? | | | Yes | No |
| **C.4.3.1** | If yes, please specify any identified risk factors: | | | | |

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| **C.5** | **Somatic Cell Clinical Trial product** | | N/A |
| **C.5.1** | Origin of cells: | | |
| **C.5.1.1** | Autologous | Yes | No |
| **C.5.1.2** | Allogeneic | Yes | No |
| **C.5.2** | Type of cells: |  |  |
| **C.5.2.1** | Stem cells | | |
| **C.5.2.2** | Differentiated cells | | |
| **C.5.2.2.1** | If yes, please specify: | Yes | No |
| **C.5.2.3** | Other | Yes | No |
| **C.5.2.3.1** | If yes, please specify: | | |

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| **C.6** | **Gene Therapy Investigational Product (No genetic modification)** | | N/A |
| **C.6.1** | Gene(s) of interest: | | |
| **C.6.2** | In vivo gene therapy? | Yes | No |
| **C.6.3** | Ex vivo gene therapy? | Yes | No |
| **C.6.4** | Type of gene transfer product: | | |
| **C.6.4.1** | Nucleic acid (e.g. plasmid). If yes, please specify if; | Yes | No |
| **C.6.4.1.1** | Naked | Yes | No |
| **C.6.4.1.2** | Complexed | Yes | No |
| **C.6.4.2** | Viral vector | Yes | No |
| **C.6.4.2.1** | If yes, specify the type: (e.g. adenovirus, retrovirus, AAV): | | |
| **C.6.4.3** | Others: | Yes | No |
| **C.6.4.3.1** | If yes, specify: | | |
| **C.6.5** | Genetically modified somatic cells? | Yes | No |
| **C.6.5.1** | The origin of the cells; | | |
| **C.6.5.1.1** | Autologous | Yes | No |
| **C.6.5.1.2** | Allogeneic | Yes | No |
| **C.6.5.1.3** | Xenogeneic | Yes | No |
| **C.6.5.1.3.1** | If yes, please specify species of origin: | | |
| **C.6.5.2** | Specify type of cells (hematopoietic stem cells…): | | |

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| **C.7** | **Tissue Engineered Product** | | N/A |
| **C.7.1** | Origin of cells: | | |
| **C.7.1.1** | Autologous | Yes | No |
| **C.7.1.2** | Allogeneic | Yes | No |
| **C.7.1.3** | Xenogeneic | Yes | No |
| **C.7.1.3.1** | If yes, please specify species of origin: | | |
| **C.7.2** | Type of cells: | | |
| **C.7.2.1** | Stem cells | Yes | No |
| **C.7.2.2** | Differentiated cells | Yes | No |
| **C.7.2.2.1** | If yes, specify the type (e.g. keratinocytes, fibroblasts, chondrocytes): | | |
| **C.7.2.3** | Other: | Yes | No |
| **C.7.2.3.1** | If yes, please specify: | | |

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| **C.8** | **Products Containing Devices (e.g. medical devices, scaffolds etc.)** | | N/A |
| **C.8.1** | Give a brief description of the device : | | |
| **C.8.2** | What is the name of the device? | | |
| **C.8.3** | Does this product contain: | | |
| **C.8.3.1** | A medical device? | Yes | No |
| **C.8.3.1.1** | Does this medical device have a CE mark? | Yes | No |
| **C.8.3.1.1.1** | If yes, the notified body is: | | |
| **C.8.3.2** | Bio-materials? | Yes | No |
| **C.8.3.3** | Scaffolds? | Yes | No |
| **C.8.3.4** | Matrices? | Yes | No |
| **C.8.3.5** | Other? | Yes | No |
| **C.8.3.5.1** | If yes, please specify: | | |

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| **C.9** | **Information on Placebo** *(repeat as necessary)* | | N/A |
| **C.9.1** | Is there a placebo? | Yes | No |
| **C.9.2** | This refers to the IP number: | | |
| **C.9.3** | Pharmaceutical form (use standard terms): | | |
| **C.9.4** | Route of administration (use standard terms): | | |
| **C.9.5** | Which IP is it a placebo for? Specify IP Number(s) from C.1.1: | | |
| **C.9. 5.1** | Composition, apart from the active substance(s): | | |
| **C.9.5.2** | Is it otherwise identical to the IP? | Yes | No |
| **C.9.5.2.1** | If not, specify major ingredients: | | |

1. **GENERAL INFORMATION ON THE STUDY**

*This section should be used to provide information about the aims, scope and design of the study. When the protocol includes a sub-study concerned section D.2.3 should be completed providing information about the sub-study. To identify it check the sub-study box in the ‘Objective of the trial’ question below.*

|  |  |  |  |
| --- | --- | --- | --- |
| **D.1** | **Medical Condition or Disease Under Investigation** | | |
| **D.1.1** | Specify the medical condition(s) to be investigated[[3]](#footnote-3) (free text): | | |
| **D.1.1.1** | Medical condition in easily understood language: | | |
| **D.1.1.2** | Therapeutic area: | | |
| **D.1.2** | MedDRA (ICD 10) level, term and classification code[[4]](#footnote-4)(repeat as necessary): | | |
| **D.1.3** | Are any of the conditions being studied a rare disease? | Yes | No |

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| **D.2** | **General Issues:** | | |
| **D.2.1** | Does the study involve the creation or use of a human gamete, a human embryo or a hybrid embryo? | Yes | No |
| **D.2.2** | Does the study involve the collection, storage or use of human tissue? | Yes | No |
| **D.2.3** | Does the study involve the use or disclosure of health information? | Yes | No |
| **D.2.4** | Does the study involve evaluating a low-risk medical device? | Yes | No |
| **D.2.5** | Does the study involve any of the following? *(select all that apply)* |  |  |
| **D.2.5.1** | A new medicine (an investigational product which doesn’t have marketing authorization) | Yes | No |
| **D.2.5.2** | An approved medicine being used for a new indication or through a new mode of administration | Yes | No |
| **D.2.5.3** | A new surgical intervention | Yes | No |
| **D.2.5.4** | One or more participants who will not have given informed consent to participate | Yes | No |
| **D.2.5.5** | One or more participants who are vulnerable (that is, who have a restricted ability to make independent decisions about their participation) | Yes | No |
| **D.2.5.6** | Standard treatment being withheld from one or more participants | Yes | No |
| **D.2.5.7** | The storage, preservation or use of human tissue without consent | Yes | No |
| **D.2.5.8** | Future unspecified use of tissue | Yes | No |

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| **D.3** | **Objective of the Study** | | |
| **D.3.1** | Main objective: please refer to study synopsis and protocol | | |
| **D.3.2** | Secondary objectives: please refer to study synopsis and protocol | | |
| **D.3.3** | Is there a sub-study? | Yes | No |
| **D.3.3.1** | If yes give the full title, date and version of each sub-study and their related objectives: | | |

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| **D.4** | **Principal inclusion criteria *(list the most important)*** |
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| **D.5** | **Principal exclusion criteria *(list the most important)*** |
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| **D.6** | **End point(s):** |
| **D.6.1** | Primary end point of the study(repeat as necessary)[[5]](#footnote-5)**:** |
| **D.6.1.1** | Timepoint(s) of evaluation of this endpoint: |
| **D.6.2** | Secondary end point of the study(repeat as necessary): |
| **D.6.2.1** | Timepoint(s) of evaluation of this endpoint: |

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| **D.7** | **Scope of the study *(****Tick all boxes where applicable)* | |
| **D.7.1** | Diagnosis |  |
|  | Early detection/screening |  |
| **D.7.2** | Prophylaxis |  |
| **D.7.3** | Therapy |  |
| **D.7.4** | Safety |  |
| **D.7.5** | Efficacy |  |
| **D.7.6** | Pharmacokinetic |  |
| **D.7.7** | Pharmacodynamic |  |
| **D.7.8** | Bioequivalence |  |
| **D.7.9** | Dose Response |  |
| **D.7.10** | Pharmacogenetic |  |
| **D.7.11** | Pharmacogenomic |  |
| **D.7.12** | Pharmacoeconomic |  |
| **D.7.13** | Other |  |
| **D.7.13.1** | If yes, please specify: Identification of biomarkers | |

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| --- | --- | --- |
| **D.8** | **Type of the study** | |
| **D.8.1** | Human pharmacology (Phase I) |  |
| **D.8.1.1** | First administration to humans |  |
| **D.8.1.2** | Bioequivalence study |  |
| **D.8.1.3** | Other |  |
| **D.8.1.3.1** | If other, please specify: | |
| **D.8.2** | Therapeutic exploratory (Phase II) |  |
| **D.8.3** | Therapeutic confirmatory (Phase III) |  |
| **D.8.4** | Therapeutic use/Post Marketing(Phase IV) |  |

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| **D.9** | **Design of the study** | | | | | | | | |
| **D.9.1** | Blinding: | open- label | single- blind | | | | double- blind | | |
| **D.9.2** | Arms: | 1-arm | 2-arm  multiple-arm | | | | | | |
| **D.9.3** | Control: | placebo-controlled | | | active-controlled | | | uncontrolled | |
| **D.9.4** | Randomisation: | randomised | | non-randomised | | | | | |
| **D.9.5** | Aim: | superiority | | equivalence | | non-inferiority | | | none |

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| **D.10** | **Risks vs. benefit analysis** | | |
| **D.10.1** | Check and summarize the nature of foreseeable risks for study subjects. | | |
| **D.10.2** | Physical risks | Yes | No |
| **D.10.3** | If yes, please describe: | | |
| **D.10.4** | Social risks | Yes | No |
| **D.10.5** | If yes, please describe: | | |
| **D.10.6** | Psychological risks | Yes | No |
| **D.10.7** | If yes, please describe: | | |
| **D.10.8** | Please summarize the measures that will be taken to minimize risks identified: | | |
| **D.10.9** | Please summarize the nature of the benefits for each group of subjects and for humanity (e.g. the community, future people with the condition being studied: | | |
| **D.10.10** | Please explain how benefits overweight risks: | | |

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| --- | --- | --- | --- |
| **D.11** | **Study sites** | | |
| **D.11.1** | There is only one site in Bahrain concerned | Yes | No |
| **D.11.2** | There are multiple sites in Bahrain concerned | Yes | No |
| **D.11.3** | Total number of sites: | | |
| **D.11.4** | Names of sites: | | |
| **D.11.5** | Study involves sites outside Bahrain | Yes | No |
| **D.11.6** | Name of countries involved: | | |

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| **D.12** | **Independent data monitoring committee** | | |
| **D.12.1** | Study has an independent data monitoring committee | Yes | No |
| **D.12.2** | If yes, specify its structure and contact information: | | |

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| **D.13** | **Duration of the study** |
| **D.13.1** | Definition of the end of the study [[6]](#footnote-6): |
| **D.13.2** | Initial estimation regarding the duration of the study in Bahrain(years ,months and days):[[7]](#footnote-7) |
| **D.13.3** | Initial estimation regarding the duration of the study in all countries(years ,months and days): |
| **D.13.4** | Proposed date of starting recruitment in Bahrain: |
| **D.13.5** | Proposed date of starting recruitment in all countries: |

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| **D.14** | **Ethical issues** | | |
| **D.14.1** | Has an application for this study ( or a substantially similar study) previously declined by any ethics committee including Bahrain and other countries? | Yes | No |
| **D.14.2** | Please provide a brief summary of the main ethical issues that you believe your study may raise (free text): | | |

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| **D.15** | **Reporting and dissemination of results** | | | |
| **D.** | How do you intend to report or disseminate the results of the study? | | | |
| **D.15.1** | Article(s) in peer-reviewed scientific journals | | |  |
| **D.15.2** | Internal reports | | |  |
| **D.15.3** | Conference presentations | | |  |
| **D.15.4** | Submission to regulatory authorities (e.g. FDA, EMA, Medsafe) | | |  |
| **D.15.5** | Other | | |  |
| **D.15.5.1** | If yes, please specify: | | | |
| **D.15.6** | No plans to report or disseminate results | | |  |
| **D.15.7** | Will any restrictions be placed (for example, by the sponsor or funder) on the publication of the results of the clinical study? | Yes | No | |
| **D.15.8** | If yes, please briefly describe these restrictions and explain why they are in place: | | | |
| **D.15.9** | Will you inform subjects about the results of the study? | Yes | No | |
| **D.15.9.1** | Please either explain how you will inform subjects or explain why you don’t intend to do so: | | | |

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| **D.16** | **Arrangements for monitoring serious adverse events** | |
| **D.16** | How will serious adverse events occurring in the study be monitored? | |
| **D.16.1** | Independent data safety monitoring committee |  |
| **D.16.2** | Internal data safety monitoring committee |  |
| **D.16.3** | Other data safety monitoring arrangements |  |
| **D.16.4** | No formal data safety monitoring arrangements |  |

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| --- | --- | --- |
| **D.** | **Participant incentives** *( please check all apply)* | |
| **D.17.1** | Cash |  |
| **D.17.2** | Check |  |
| **D.17.3** | Raffle/lottery |  |
| **D.17.4** | Gift |  |
| **D.17.5** | Food |  |
| **D.17.6** | Other |  |
| **D.17.6.1** | If yes, please specify: | |

1. **POPULATION OF STUDY SUBJECTS please refer to study synopsis and protocol**

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| --- | --- | --- | --- |
| **E.1** | **Age range** *(Please**specify the estimated number of subjects planned in each age range for the study*[[8]](#footnote-8)*)* | | |
| **E.1.1** | In Utero – Approx. Number of subjects: | Yes | No |
| **E.1.2** | Preterm Newborn Infants (up to gestational age < 37 weeks) – Approx. number of subjects: | Yes | No |
| **E.1.3** | Newborns (0-27 days) – Approx. number of subjects: | Yes | No |
| **E.1.4** | Infants and toddlers (28 days - 23 months)– Approx. number of subjects: | Yes | No |
| **E.1.5** | Children (2-11 years)– Approx. number of subjects: | Yes | No |
| **E.1.6** | Adolescents (12-17 years)– Approx. number of subjects: | Yes | No |
| **E.1.7** | Adults (18-64 years)- Approx. number of subjects: | Yes | No |
| **E.1.8** | Elderly (>= 65 years)- Approx. number of subjects: | Yes | No |
| **E.2** | **Gender** | | |
| **E.2.1** | Female | |  |
| **E.2.2** | Male | |  |

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| **E.3** | **Subject Population** | | |
| **E.3.1** | Healthy volunteers | Yes | No |
| **E.3.2** | Patients | Yes | No |
| **E.3.3** | Specific vulnerable populations | Yes | No |
| **E.3.3.1** | Women of child bearing potential not using contraception | Yes | No |
| **E.3.3.2** | Women of child bearing potential using contraception | Yes | No |
| **E.3.3.3** | Pregnant women | Yes | No |
| **E.3.3.4** | Nursing women | Yes | No |
| **E.3.3.5** | Emergency situation | Yes | No |
| **E.3.3.6** | Subjects incapable of giving consent personally | Yes | No |
| **E.3.3.6.1** | If yes, specify: | | |

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| **E.4** | **Planned number of subject to be included** |
| **E.4.1** | In Bahrain: |
| **E.4.2** | In the whole clinical study: |

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| **E.5** | **Plans for treatment and care after a subject has ended his/her participation in the study** | | |
| **E.5.1** | Please specify (free text): | | |
| **E.5.2** | Will all subjects have continued access to the best-proven intervention after the end of the study? | Yes | No |

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| **E.6** | **Informed consent process** | |
| **E.6** | Please check which applies: | |
| **E.6.1** | Informed consent will be obtained from subjects and documented with a signed, written consent form |  |
| **E.6.2** | Informed consent will be obtained from subjects, but no signed consent form will be used. This includes oral consent and implied consent. |  |
| **E.6.3** | Fully informed consent will not be obtained from all subjects. This includes deception, withholding information etc. |  |
| **E.6.4** | Please describe the consent process for each group of subjects. Specifically explain **who** is obtaining consent, **when** and **where** the consent will be obtained : | |
| **E.6.5** | If the study involves potentially vulnerable population who have a restricted ability to make independent decision about their participation, please explain how the study’s informed consent process takes needs of these people into account (free text) : | |
| **E.6.6** | What are the primary languages of the participants? | |

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| **E.7** | **Recruitment** |
| **E.7.1** | How will individuals in each group of subjects be identified? Explain how privacy and confidentiality is protected during the identification of participants: |
| **E.7.2** | Describe the recruitment process for each group of potential subjects. Explain who will recruit potential participants and where/how contact will be made: |
| **E.7.2** | Explain how the recruitment of subjects is done in a manner that protects their confidentiality and that minimizes the possibility of undue influence or coercion to take part in the research: |
| **E.7.3** | What type of materials (advertisements, brochures, recruitment scripts etc.) will be used to recruit potential subjects?: |

1. **CLINICAL STUDY SITES/INVESTIGATORS AND OTHER FACILITIES**

|  |  |  |
| --- | --- | --- |
| **F.1** | **Site number (1)** | |
| **F.1.1** | Site Name: | |
| **F.1.2** | **Principal Investigator:** | |
| **F.1.2.1** | Name-surname: | |
| **F.1.2.2** | Qualification: | |
| **F.1.2.3** | Institution name: | |
| **F.1.2.4** | Institution department: | |
| **F.1.2.5** | Institution address: | |
| **F.1.2.6** | Telephone number: | |
| **F.1.2.7** | Fax number: | |
| **F.1.2.8** | E-mail: | |
| **F.1.3** | **Co-investigator:** *(repeat as necessary)* | N/A |
| **F.1.3.1** | Name-surname: | |
| **F.1.3.2** | Qualification: | |
| **F.1.3.3** | Institution name: | |
| **F.1.3.4** | Institution department: | |
| **F.1.3.5** | Institution address: | |
| **F.1.3.6** | Telephone number: | |
| **F.1.3.7** | Fax number: | |
| **F.1.3.8** | E-mail: | |
| **F.1.4** | **Sub-investigator:** *(repeat as necessary)* | |
| **F.1.4.1** | Name-surname: | |
| **F.1.4.2** | Qualification: | |
| **F.1.4.3** | Institution name: | |
| **F.1.4.4** | Institution department: | |
| **F.1.4.5** | Institution address: | |
| **F.1.4.6** | Telephone number: | |
| **F.1.4.7** | Fax number: | |
| **F.1.4.8** | E-mail: | |

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| **F.1** | **Site number (2)** | |
| **F.1.1** | Site Name: | |
| **F.1.2** | **Principal Investigator:** | |
| **F.1.2.1** | Name-surname: | |
| **F.1.2.2** | Qualification: | |
| **F.1.2.3** | Institution name: | |
| **F.1.2.4** | Institution department: | |
| **F.1.2.5** | Institution address: | |
| **F.1.2.6** | Telephone number: | |
| **F.1.2.7** | Fax number: | |
| **F.1.2.8** | E-mail: | |
| **F.1.3** | **Co-investigator:** *(repeat as necessary)* | N/A |
| **F.1.3.1** | Name-surname: | |
| **F.1.3.2** | Qualification: | |
| **F.1.3.3** | Institution name: | |
| **F.1.3.4** | Institution department: | |
| **F.1.3.5** | Institution address: | |
| **F.1.3.6** | Telephone number: | |
| **F.1.3.7** | Fax number: | |
| **F.1.3.8** | E-mail: | |
| **F.1.4** | **Sub-investigator:** *(repeat as necessary)* | |
| **F.1.4.1** | Name-surname: | |
| **F.1.4.2** | Qualification: | |
| **F.1.4.3** | Institution name: | |
| **F.1.4.4** | Institution department: | |
| **F.1.4.5** | Institution address: | |
| **F.1.4.6** | Telephone number: | |
| **F.1.4.7** | Fax number: | |
| **F.1.4.8** | E-mail: | |

**LABORATORIES AND TECHNICAL FACILITIES USED IN THE STUDY**

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| **F.2** | **Central Technical Facilities To Be Used in the Conduct of the Study** *(Laboratory or other technical facilities, in which the measurement or assessment of the main evaluation criteria are centralised)* |
| **F.2.1** | Name of the facility: |
| **F.2.2** | Department: |
| **F.2.3** | Contact Person: |
| **F.2.3.1** | Name-surname: |
| **F.2.3.2** | Position: |
| **F.2.3.3** | Address: |
| **F.2.3.4** | Telephone number: |
| **F.2.3.5** | Fax number: |
| **F.2.3.6** | E-mail: |
| **F.2.4** | Duties subcontracted: |

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| **F.2** | **Central Technical Facilities To Be Used in the Conduct of the Study** *(Laboratory or other technical facilities, in which the measurement or assessment of the main evaluation criteria are centralised)* |
| **F.2.1** | Name of the facility: |
| **F.2.2** | Department: |
| **F.2.3** | Contact Person: |
| **F.2.3.1** | Name-surname: |
| **F.2.3.2** | Position: |
| **F.2.3.3** | Address: |
| **F.2.3.4** | Telephone number: |
| **F.2.3.5** | Fax number: |
| **F.2.3.6** | E-mail: |
| **F.2.4** | Duties subcontracted: |

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| **F.2** | **Central Technical Facilities To Be Used in the Conduct of the Study** *(Laboratory or other technical facilities, in which the measurement or assessment of the main evaluation criteria are centralised)* |
| **F.2.1** | Name of the facility: |
| **F.2.2** | Department: |
| **F.2.3** | Contact Person: |
| **F.2.3.1** | Name-surname: |
| **F.2.3.2** | Position: |
| **F.2.3.3** | Address: |
| **F.2.3.4** | Telephone number: |
| **F.2.3.5** | Fax number: |
| **F.2.3.6** | E-mail: |
| **F.2.4** | Duties subcontracted: |

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| **F.3** | **TISSUES AND BIOLOGICAL SAMPLES** | | |
| **F.3** | **Does the study requires the collection and shipment overseas of:** | | |
| **F.3.1** | Subject Blood or Plasma | Yes | No |
| **F.3.2** | Subject Cells or Tissues | Yes | No |
| **F.3.3** | DNA or any other genetic material | Yes | No |
| **F.3.3.1** | If yes, specify: | | |
| **F.3.4** | Name of the Laboratory: | | |
| **F.3.4.1** | Contact Person: | | |
| **F.3.4.2** | Position: | | |
| **F.3.4.3** | Address: | | |
| **F.3.4.4** | Telephone number: | | |
| **F.3.4.5** | Fax number: | | |
| **F.3.4.6** | E-mail: | | |
| **F.3.5** | Activities carried out by the overseas laboratory: | | |

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| **F.4** | **Networks To Be Involved in the Study***(E.g. Paediatric Networks, Patients’ Associations, Medical Associations, or other involved in the study)* | N/A |
| **F.4.1** | Name of the organisation: | |
| **F.4.2** | Contact Person: | |
| **F.4.2.1** | Name-surname: | |
| **F.4.2.2** | Position: | |
| **F.4.2.3** | Address: | |
| **F.4.2.4** | Telephone number: | |
| **F.4.2.5** | Fax number: | |
| **F.4.2.6** | E-mail: | |
| **F.4.3** | Activities carried out by the network: | |

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| **F.5** | **Organisations To Whom the Sponsor Has Transferred Study Related Duties and Functions** | | |
| **F.5.1** | Has the sponsor transferred any major or all the sponsor’s study related duties and functions to another organisation or third party? | Yes | No |
| **F.5.2** | Name of the organisation: | | |
| **F.5.3** | Contact Person: | | |
| **F.5.3.1** | Name-surname: | | |
| **F.5.3.2** | Position: | | |
| **F.5.3.3** | Address: | | |
| **F.5.3.4** | Telephone number: | | |
| **F.5.3.5** | Fax number: | | |
| **F.5.3.6** | E-mail: | | |
| **F.5.4** | Duties subcontracted: | Yes | No |
| **F.5.4.1** | All tasks of the sponsor | Yes | No |
| **F.5.4.2** | Monitoring | Yes | No |
| **F.5.4.3** | Regulatory (e.g. preparation of applications) | Yes | No |
| **F.5.4.4** | Investigator recruitment | Yes | No |
| **F.5.4.5** | IVRS16 – treatment randomisation | Yes | No |
| **F.5.4.6** | Data management | Yes | No |
| **F.5.4.7** | E-data capture | Yes | No |
| **F.5.4.8** | SUSAR reporting | Yes | No |
| **F.5.4.9** | Quality assurance auditing | Yes | No |
| **F.5.4.10** | Statistical analysis | Yes | No |
| **F.5.4.11** | Medical writing | Yes | No |
| **F.5.4.12** | Other duties subcontracted | Yes | No |
| **F.5.4.12.1** | If yes, please specify: | | |

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| **F.6** | **Safety Monitor** |
| **F.6.1** | Name-surname: |
| **F.6.2** | Title: |
| **F.6.3** | Address: |
| **F.6.4** | Telephone number: |
| **F.6.5** | Fax number: |
| **F.6.6** | E-mail: |

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| **F.7** | **Clinical Monitor** |
| **F.7.1** | Name-surname: |
| **F.7.2** | Title: |
| **F.7.3** | Address: |
| **F.7.4** | Telephone number: |
| **F.7.5** | Fax number: |
| **F.7.6** | E-mail: |

1. **SIGNATURE OF THE APPLICANT**

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| * 1. I hereby confirm that : * Information provided is complete; * The attached documents contain an accurate account of the information available; * The clinical study will be conducted in accordance with the protocol; NHRA Regulation and ICH-GCP * Safety and result-related information will be reported in accordance with NHRA Requirements |

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| * 1. **Sponsor of the Request for Clinical Trial Authorization** |
| * + 1. Date:     2. Signature:     3. Print name: |

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| * 1. **Applicant/Legal Representative of the Request for Clinical Trial Authorization if any** |
| * + 1. Date:     2. Signature:     3. Print name: |

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| * 1. **CRO of the Request for Clinical Trial Authorization** |
| * + 1. Date:     2. Signature:     3. Print name: |

1. Exception is made to the Clinical Trial Agreement that could be submitted in a draft form. [↑](#footnote-ref-1)
2. Complete also section C.5. [↑](#footnote-ref-2)
3. In the case of healthy volunteer studies, the intended indication for the product under development should be provided. [↑](#footnote-ref-3)
4. Applicants are encouraged to provide the MedDRA lower level term if applicable and classification code. Alternatively use ICD 10 Disease Classification Terminology [↑](#footnote-ref-4)
5. The protocol will usually identify a single primary end point but there may be a co-primary end point in some cases and/or a number of secondary end points. [↑](#footnote-ref-5)
6. If it is the last visit of the last subject, please enter “LVLS”. If it is not LVLS provide the definition. [↑](#footnote-ref-6)
7. From the first inclusion until the end of the study. [↑](#footnote-ref-7)
8. Total number of subjects will be an initial estimate. The numbers of subjects whose inclusion is authorized are those set out in the authorized version of the protocol, or subsequent authorized amendments. [↑](#footnote-ref-8)