**ARAHAN:**

INSTRUCTION:

1. **Borang permohonan hendaklah ditaip dan dicetak atas kertas A4 putih depan dan belakang kecuali lampiran A, B dan C dicetak berasingan (muka depan sahaja). Lampiran D hanya perlu dicetak bagi kajian klinikal yang melibatkan *First-In Human.***

Application form should be typed and printed on both sides using white A4 size paper except Appendix A, B, and C to be printed separately (single sided only). Appendix D should only be printed for First-In Human clinical trial application.

1. **Borang permohonan yang dikemukakan hendaklah dalam salinan asal.**

The submitted application form should be in original copy.

1. **Sila rujuk *Malaysian* *Guideline for the Application of Clinical Trial Import Licence and Clinical Trial Exemption* edisi terkini untuk maklumat lanjut.**

Please refer to latest edition of Malaysian Guideline for the Application of Clinical Trial Import Licence and Clinical Trial Exemption for more information.

**BAHAGIAN 1 BUTIRAN PENAJA**

PART 1 SPONSOR’S DETAILS

|  |  |  |
| --- | --- | --- |
| **1.1** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **1.2** | **Nama organisasi**  Name of organisation |  |
| **1.3** | **Alamat organisasi**  Address of organisation |  |
| **1.4** | **Nombor telefon**  Telephone number |  |
| **1.5** | **Alamat emel**  Email address |  |

**BAHAGIAN 2 BUTIRAN PEMOHON**

PART 2 APPLICANT’S DETAILS

|  |  |  |
| --- | --- | --- |
| **2.1** | **Sila tanda pada kotak yang berkaitan:**  Please tick the appropriate box: | |
|  | **Penaja**  Sponsor |
|  | **Orang atau organisasi yang diberi kuasa oleh penaja untuk memohon**  Person or organisation authorised by the sponsor to make the application |

|  |  |  |
| --- | --- | --- |
| **2.2** | **Nama pemohon**  Name of applicant |  |
| **2.3** | **Nombor kad pengenalan**  Identity card number |  |
| **2.4** | **Nama organisasi**  Name of organisation |  |
| **2.5** | **Alamat organisasi**  Address of organisation |  |
| **2.6** | **Nombor telefon**  Telephone number |  |
| **2.7** | **Alamat emel**  Email address |  |

**Sila isikan butiran individu kedua untuk dihubungi, sekiranya ada.**

Please fill in the details of the second contact person, if necessary.

|  |  |  |
| --- | --- | --- |
| **2.8** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **2.9** | **Nombor telefon**  Telephone number |  |
| **2.10** | **Alamat emel**  Email address |  |

**BAHAGIAN 3 BUTIRAN PRODUK KAJIAN**

PART 3 INVESTIGATIONAL PRODUCT’S (IP) DETAILS

**Maklumat bagi setiap produk kajian yang memerlukan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal termasuk setiap *comparator* dan setiap placebo perlu diisi di bawah Bahagian 3.**

**Sekiranya percubaan klinikal melibatkan lebih daripada satu produk kajian, sila lengkapkan 3.1 hingga 3.23 dan ulang untuk setiap produk kajian serta beri nombor turutan seperti A1, A2, A3 dan seterusnya. Maklumat berkenaan placebo hendaklah diisi di bawah D) Butiran Placebo sekiranya ada.**

Information on all IP that require Clinical Trial Exemption (CTX) including each comparator and each placebo should be provided in this part.

If the trial is performed with several products that require CTX, please complete 3.1 to 3.23 of this part and repeat for each IP and give each IP a sequential number in A1, A2, A3 etc. Information on placebo must be filled at part D) Details on placebo, if applicable.

**A) Pengenalan Produk Kajian**

A) Identification of IP

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **3.1** | **Nombor rujukan Produk Kajian**  **(contohnya, A1, A2, A3 dan seterusnya)**  Reference number of IP  (e.g. A1, A2, A3 etc.) | | | |  | | |
| **3.2** | **Kegunaan produk kajian**  Use of IP | | | | | | |
|  | | **Produk kajian yang diuji**  IP being tested | | | | |
|  | | **Produk kajian yang digunakan sebagai comparator**  IP used as a comparator | | | | |
| **3.3** | | **Jenis Produk Kajian**  Type of IP | | | | | | |
|  | | **Bahan kimia**  Chemical origin | |  | **Biologik/ bioteknologi**  Biological / biotechnological origin | |
|  | | **Vaksin**  Vaccine | |  | **Lain-lain, sila nyatakan:**  Others, please specify: | |

**B) Deskripsi Produk Kajian**

B) Description of IP

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **3.4** | | **Nama Produk**  Product name |  | |
| **3.5** | | **Kod Produk, jika berkenaan1**  Product code, where applicable1 |  | |
| **3.6** | | **Nama produk dicetak pada Kebenaran Mengilang**  **(termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX  (includes name, dosage form and strength) |  | |
| **3.7** | | **Kod ATC, sekiranya telah berdaftar**  ATC code, if officially registered |  | |
| **3.8** | | **Nama bahan aktif (INN atau INN dicadangkan sekiranya ada)**  Name of each active substance (INN or proposed INN if available) |  | |
| **3.9** | | **Kekuatan dan unit kepekatan (nyatakan semua kekuatan yang akan digunakan serta saiz vial/isipadu akhir sekiranya berkaitan)**  Strength and concentration unit (specify all strengths to be used and vial size/final volume if applicable) |  | | |
| **3.10** | | **Bentuk dosej**  Dosage form (use standard terms) |  | | |
| **3.11** | | **Adakah bentuk dos dan bahan aktif yang digunakan mengandungi sumber yang dianggap *culturally unacceptable*?**  Does the dosage form or active ingredient contain source/ origin that may be culturally unacceptable? | Yes  No | | |
|  | **Sekiranya ada, sila nyatakan**  If yes, please specify the source |  | | |
| **3.12** | | **Laluan pemberian ubat**  Route of administration |  | | |
| **3.13** | | **Data Stabiliti *Representative Batch* (*Condition* & Tempoh)**  Stability Data Representative Batch (Condition & Duration) | Real Time Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_\_ months | Accelerated Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_\_ months | |
| **3.14** | | **Tempoh penyimpanan yang dicadang**  Proposed shelf life |  | | |
| **3.15** | | **Keadaan Penyimpanan**  Storage condition |  | | |
| **3.16** | | **Cara tindakan** (max 10 garis)  Mode of action (max 10 lines) |  | | |
| **3.17** | **Maklumat pengilang**  Information of manufacturer | Name and address of manufacturer:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers | | |
| **3.18** | **Dokumen dikemukakan**  Submitted documents | Pharmaceutical Data of Drug Substance and Drug Product  Certificate of Analysis of Drug Substance and Drug Product  Stability Data  IP Label | | |

**1Hendaklah diisi sekiranya produk kajian tersebut tiada nama produk. Ini merujuk kepada nama yang digunakan oleh pihak penaja untuk mengenalpasti produk kajian dalam dokumen percubaan klinikal (contohnya, protokol, brosur penyelidik dan sebagainya)**

To be provided only when there is no product name. This is the code designated by the sponsor to represent the name routinely used by the sponsor to identify the IP in the clinical trial documentation (e.g. protocol, investigator’s brochure etc.).

**C) Status Pendaftaran Produk**

C) Product Registration status

|  |  |  |
| --- | --- | --- |
| **3.19** | **Adakah produk kajian yang digunakan adalah produk berdaftar dengan PBKD?**  Is this IP to be used in the trial a registered product with DCA? | Yes  No |
| **Sekiranya ada, sila nyatakan nama dagangan dan Nombor Pendaftaran Produk**  If yes, please specify the trade name and Product Registration number |  |
| **3.20** | **Adakah produk kajian akan didaftarkan di Malaysia?**  Is this product going to be registered in Malaysia | Yes  No |
| **3.21** | **Adakah produk kajian yang digunakan adalah produk berdaftar di luar negara?**  Is this IP to be used in the trial a registered product overseas? | Yes  No |
| **Sekiranya ada, sila nyatakan nama negara serta nama dagangan produk**  If yes, please specify the country name and product’s trade name |  |
| **3.22** | **Adakah produk kajian berbeza daripada yang telah berdaftar?**  Is the IP modified compared to the registered form? | Yes  No |
| **Jika ya, sila nyatakan:**  If yes, please specify: |  |
| **3.23** | **Adakah produk kajian pernah mempunyai Kebenaran Mengilang?**  Does this IP have CTX?  **Jika ya, sila lengkapkan maklumat di bawah:**  If yes, please complete the following details: | Yes  No |
| **Nama Produk Kajian (seperti di dalam Kebenaran Mengilang )**  IP Name (as per CTX) |  |
| **Nombor Kebenaran Mengilang**  CTX Number | CTX- \_\_ \_\_ \_\_ |
| **Tarikh Luput Kebenaran Mengilang**  CTX Expiry Date  **(dd/mm/yyyy)** | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |

**D) Butiran *Placebo***

D) Details on Placebo

**Sekiranya percubaan klinikal melibatkan lebih daripada satu placebo, sila beri nombor turutan seperti D1, D2, D3 dan seterusnya, serta lengkapkan 3.24 hingga 3.32 untuk setiap placebo.**

If the trial is performed with several placebos that require CTX, please give each placebo a sequential number in D1, D2, D3 etc and complete 3.24 to 3.32 of this part for each placebo.

|  |  |  |
| --- | --- | --- |
| **3.24** | **Adakah percubaan klinikal ini melibatkan *placebo***?  Is there a placebo involved in this clinical trial? | Yes  No |
| **3.25** | **Nombor rujukan *Placebo***  **(contohnya, D1, D2, D3 dan seterusnya)**  Reference number of placebo  (e.g. D1, D2, D3 etc.) |  |
| **3.26** | **Sila nyatakan *placebo* ini adalah untuk nombor produk Kajian yang berkaitan (contohnya, A1, A2, A3 dan seterusnya)**  Please specify the IP Number (e.g. A1, A2, A3 etc.) for this *placebo* |  |
| **3.27** | **Nama produk dicetak pada Kebenaran Mengilang**  **(termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX  (includes name, dosage form and strength) |  |
| **3.28** | **Bentuk dosej**  Dosage form (use standard terms) |  |
| **3.29** | **Adakah bentuk dosej dan bahan aktif yang digunakan mengandungi sumber yang dianggap `culturally unacceptable’?**  Does the dosage form or active ingredient contain source/ origin that may be culturally unacceptable? | Yes  No |
| **Sekiranya ada, sila nyatakan**  If yes, please specify the source |  |
| **3.30** | **Komposisi, selain daripada bahan aktif, adalah sama dengan produk kajian**  Composition, apart from the active substance(s), is otherwise identical to the IP | Yes  No |
| **Sekiranya tidak, nyatakan bahan utama**  If not, specify major ingredients |  |
| **3.31** | **Maklumat pengilang**  Information of manufacturer | Name and address of manufacturer:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers |
| **3.32** | **Dokumen dikemukakan**  Submitted documents | Pharmaceutical Data  Certificate of Analysis  IP Label |

**E) Ubat-ubat lain yang memerlukan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal termasuk *Standard of Care (SOC)*, jika berkenaan**

E) Other medications that require CTX including Standard of Care (SOC), where applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **3.33** | | **Nama, bentuk dosej dan kekuatan**  Name, dosage form and strength | |  |
| **3.34** | | **Nama produk dicetak pada Kebenaran Mengilang**  **(termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX  (includes name, dosage form and strength) | |  |
| **3.35** | | **Bahan aktif**  Active ingredient | |  |
| **3.36** | | **Maklumat pengilang**  Information of manufacturer | | Name and address of manufacturer:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers |
| **3.37** | **Dokumen dikemukakan**  Submitted documents | | Pharmaceutical Data  Certificate of Analysis  Stability Data  IP Label | |
| **3.38** | **Adakah produk kajian yang digunakan adalah produk berdaftar dengan PBKD?**  Is this IP to be used in the trial a registered product with DCA? | | Yes  No | |
| **Sekiranya ada, sila nyatakan nama dagangan dan Nombor Pendaftaran Produk**  If yes, please specify the trade name and Product Registration number | |  | |
| **3.39** | **Adakah produk kajian berbeza daripada yang telah berdaftar?**  Is the IP modified compared to the registered form? | | Yes  No | |
| **Jika ya, sila nyatakan:**  If yes, please specify: | |  | |
| **3.40** | **Adakah produk kajian pernah mempunyai Kebenaran Mengilang?**  Does this IP have CTX?  **Jika ya, sila lengkapkan maklumat di bawah:**  If yes, please complete the following details: | | Yes  No | |
| **Nama Produk Kajian (seperti di dalam Kebenaran Mengilang )**  IP Name (as per CTX) | |  | |
| **Nombor Kebenaran Mengilang**  CTX Number | | CTX- \_\_ \_\_ \_\_ | |
| **Tarikh Luput Kebenaran Mengilang**  CTX Expiry Date  **(dd/mm/yyyy)** | | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ | |

**BAHAGIAN 4 BUTIRAN KAJIAN KLINIKAL**

PART 4 CLINICAL TRIAL’S DETAILS

|  |  |  |
| --- | --- | --- |
| **4.1** | **Nombor Pendaftaran National Medical Research Registry (NMRR)**  NMRR Registration ID | **NMRR-** |
| **4.2** | **Tajuk penuh kajian klinikal**  Full title of the clinical trial |  |
| **4.3** | **Tajuk singkatan kajian klinikal, jika ada**  Abbreviated title of the trial, where available |  |
| **4.4** | **Nombor protokol**  Protocol number |  |
| **4.5** | **Fasa**  Phase | Human Pharmacology (Phase I)  First-in Human  Bioequivalence study  Other, please specify:  Therapeutic exploratory (Phase II)  Therapeutic confirmatory (Phase III)  Therapeutic use (Phase IV) |
| **4.6** | **Anggaran jangkamasa kajian klinikal**  Estimated duration of the clinical trial |  |
| **4.7** | **Cadangan tarikh kajian bermula**  Proposed date of start of recruitment |  |
| **4.8** | **Jumlah subjek di Malaysia**  Total number of subjects in Malaysia |  |

**BAHAGIAN 5 TAPAK KAJIAN**

PART 5 TRIAL SITE

**Sekiranya percubaan klinikal melibatkan lebih daripada satu tapak kajian, sila ulang dengan melengkapkan 5.1 hingga 5.11 untuk setiap tapak kajian dan beri nombor turutan seperti T1,T2, T3 dan seterusnya.**

If the trial is performed with more than one trial site, please repeat and complete 5.1 to 5.11 of this part for each trial site and give each trial site a sequential number in T1,T2, T3 etc.

|  |  |  |
| --- | --- | --- |
| **5.1** | **Nombor rujukan tapak kajian**  **(contohnya, T1, T2, T3 dan seterusnya)**  Reference number of trial site  (e.g. T1, T2, T3 etc.) |  |
| **5.2** | **Nama tapak kajian**  Name of the trial site |  |
| **5.3** | **Alamat tapak kajian**  Address of the trial site |  |
| **5.4** | **Nama penyelidik utama**  Name of principal investigator (PI) |  |
| **5.5** | **Nombor kad pengenalan/ passport2**  Identity card/ passport number2 |  |
| **5.6** | **Profil penyelidik utama (Untuk tapak kajian di Malaysia sahaja)**  Profile of PI  (For trial site in Malaysia only) | Declaration of PI: (dd/mm/yyyy)  Curriculum vitae: (dd/mm/yyyy)  Good Clinical Practice (GCP) Certificate:  GCP Course Organiser :  Course Date : (dd/mm/yyyy) |
| **5.7** | **Maklumat penyelidik**  Contact details of investigator | |
| **Nombor telefon**  Telephone number |  |
| **Alamat Emel**  E-mail address |  |
| **Jumlah subjek yang dijangka**  Total number of subjects planned |  |
| **5.8** | **Nama Jawatankuasa Etika**  Name of the Ethics Committee |  |
| **5.9** | **Status Kelulusan daripada Jawatankuasa Etika**  Ethics Committee Approval Status | To be requested  Pending  Given  If given, please specifiy  Date of authorisation/opinion (dd/mm/yyyy):  Authorisation accepted/ favourable opinion  Not accepted/ not favourable  The reasons: |
| **5.10** | **Status Permohonan kepada Badan Regulatori (Bagi Kajian Klinikal yang dijalankan di Luar Negara sahaja)**  Regulatory Authority Application Status (Only applicable for clinical study conducted outside of Malaysia) | To be requested  Pending  Given |
| **5.11** | **Status tapak kajian *Phase 1 Unit Accreditation Programme3***  Phase 1 Unit Accreditation Programme Status3 | Provisionally Listed  Listed/Maintained |
| **5.12** | **Nama dan alamat tapak bioanalitikal4**  Name and address of bioanalytical site4 |  |

**2Untuk kajian klinikal yang dijalankan di Malaysia sahaja. Sila kemukakan nombor pasport bagi penyelidik utama bukan warganegara.**

2For clinical trial conducted in Malaysia only. Please provide passport number for non-Malaysian principal investigator.

**3Untuk kajian klinikal *First-in Human* sahaja**

3 For First-in Human clinical trial only

**4Untuk kajian bioekuivalens sahaja**

4For bioequivalence study only

**BAHAGIAN 6 NEGARA-NEGARA LAIN YANG TERLIBAT**

PART 6 OTHER PARTICIPATING COUNTRY(-IES)

|  |  |  |
| --- | --- | --- |
| **6.1** | **Status permohonan kajian klinikal di negara-negara lain**  Clinical trial application status in the other countries | |
|  | **Belum dikemukakan**  Pending submission |  |
| **Dikemukakan**  Submitted |  |
| **Lulus**  Approved |  |
| **Ditolak**  Refused |  |

**BAHAGIAN 7 KUANTITI UNTUK DIKILANG**

PART 7 QUANTITY TO BE MANUFACTURED

* 1. **Jumlah kuantiti untuk dikilang**

Total quantity to be manufactured

|  |  |  |
| --- | --- | --- |
| **Saiz Kelompok:**  Batch Size: | | |
| **Bil.**  No. | **Nama Produk\***  Name of Product\* | **Jumlah Kuantiti yang Diperlukan untuk Percubaan Klinikal**  Total Quantity Required for Clinical Trial Purpose |
|  |  |  |
|  |  |  |

**\*Mengikut unit pembungkusan primer yang akan dikilang sebagai contoh: vial, botol, blister, ampul, syringe.**

\*According to primary packaging to be manufactured for example: vial, bottle, blister, ampoule, syringe.

**7.2 Butiran Pengiraan Kuantiti dengan Justifikasi untuk Semua Subjek di Malaysia**

Detailed Calculation with Justification for All Subjects in Malaysia

|  |
| --- |
|  |

**PERAKUAN PEMOHON**

APPLICANT’S DECLARATION

**Saya, yang bernama dan beralamat di bawah sebagai wakil syarikat yang memohon, mengaku bahawa:**

I, the undersigned, hereby confirm on behalf of the company that:

1. **Segala maklumat yang dibekalkan adalah lengkap**.

The information provided is complete.

1. **Segala maklumat dalam borang permohonan ini dan dokumen-dokumen dibekalkan adalah benar dan tepat.**

All details contained in this form and attached documents are true and accurate.

1. **Saya akan bertanggungjawab sepenuhnya terhadap kualiti, efikasi dan keselamatan produk ini.**

I will be fully responsible towards the quality, efficacy and safety of this product(s).

1. **Saya akan mematuhi semua peruntukan dalam Akta Jualan Dadah 1952 (Semakan 1989), Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 serta lain-lain keperluan regulatori/ garispanduan.**

I will comply with all the relevant rules and regulations in Sale of Drugs Act 1952 (Revised 1989), Control of Drugs and Cosmetics Regulations 1984 together with other regulatory requirements/ guidelines.

|  |  |  |  |
| --- | --- | --- | --- |
| **Nama Penuh**  Full Name |  | **Jawatan**  Position |  |
| **No. Kad Pengenalan**  Identity Card No. |  | **Cop Rasmi Syarikat**  Official Stamp of the Company |  |
| **Tandatangan Pemohon**  Signature of applicant |  |
| **Tarikh (DD/MM/YY):**  Date (DD/MM/YY): |  |

**Lampiran A**

(Salinan NPRA)

# Senarai Semak Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal

|  |  |
| --- | --- |
| Nombor Protokol: |  |
| Nombor Pendaftaran NMRR: | NMRR- |

|  |  |  |  |
| --- | --- | --- | --- |
| **Bil.** | **Perkara** | **Pemohon** | **NPRA** |
|  | Jadual kandungan |  |  |
|  | Surat pengiring |  |  |
|  | Borang permohonan yang lengkap dan telah ditandatangani dan cop oleh pemohon |  |  |
|  | Sijil Pendaftaran Syarikat |  |  |
|  | Lesen Racun Jenis A/ Sijil Pengekalan Tahunan (ARC) bagi pegawai farmasi kerajaan, jika berkaitan |  |  |
|  | *Letter of Authorisation*, jika berkaitan |  |  |
|  | Surat Kelulusan Jawatankuasa Etika |  |  |
|  | Protokol untuk kajian klinikal |  |  |
|  | *Declaration by* *Investigator* (Salinan asal) |  |  |
|  | Sijil *Good Clinical Practice* bagi penyelidik untuk setiap tapak kajian |  |  |
|  | *Curriculum Vitae* bagi penyelidik untuk setiap tapak kajian |  |  |
|  | Borang persetujuan termaklum (versi asal sahaja untuk salah satu tapak kajian) |  |  |
|  | Data Farmaseutikal untuk bahan aktif dan produk |  |  |
| Sijil Analisa/ *Batch Analysis* untuk bahan aktif dan produk |  |  |
| Data Stabiliti |  |  |
|  | Label kajian untuk produk kajian |  |  |
|  | Bukti Komplians Amalan Perkilangan Baik (APB) bagi setiap pengilang |  |  |
|  | Brosur Penyelidik |  |  |
|  | *Overall risk and benefit assessment* |  |  |
|  | Salinan Dokumen Elektronik dalam bentuk CD-ROM |  |  |
|  | Dokumen tambahan yang dibekalkan, jika ada |  |  |
|  | Salinan laporan saintifik dari agensi regulatori negara lain, jika ada |  |  |
| Permohonan untuk kajian klinikal *First-in Human* sahaja: | | | |
|  | Sijil Akreditasi Unit Fasa I yang dikeluarkan oleh NPRA |  |  |
|  | Sijil/Polisi insurans bagi kajian klinikal *First-in Human* |  |  |
|  | *Declaration by Sponsor for CTIL/CTX Application Involving First-in Human Clinical Trial* (salinan asal) |  |  |

**UNTUK KEGUNAAN PEJABAT (Sila isikan bahagian ini sekiranya permohonan ini diterima)**

|  |  |  |
| --- | --- | --- |
| Tandatangan & cop pegawai | Cop tarikh penerimaan | Penyerahan dokumen oleh:  Nama:  Syarikat/CRO: |

**Lampiran B**

(Salinan Pemohon)

**Pengesahan Penerimaan Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal**

Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal seperti butiran di bawah telah diterima.

|  |  |
| --- | --- |
| Nombor Protokol |  |
| Nama produk | **1.**  **2.** |
| Nombor Pendaftaran NMRR | NMRR- |

|  |  |  |
| --- | --- | --- |
| Tandatangan & cop pegawai | Cop tarikh penerimaan | Penyerahan dokumen oleh:  Nama:  Syarikat/CRO: |

**Lampiran C**

**Pengesahan Penolakan Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal Semasa Penyaringan**

Arahan:

1. Lampiran ini hendaklah disimpan bersama-sama permohonan ini.
2. Sila cetak lampiran baru bagi setiap penyaringan.

|  |  |
| --- | --- |
| Nombor Protokol |  |
| Nama produk | **1.**  **2.** |
| Nombor Pendaftaran NMRR | NMRR- |

Bagi penyaringan yang dibuat terhadap permohonan ini, berikut adalah dokumen-dokumen yang perlu dibekalkan oleh pemohon dalam penyaringan yang seterusnya:

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| Tandatangan & cop pegawai  Tarikh |

**LAMPIRAN D MAKLUMAT TAMBAHAN BAGI KAJIAN KLINIKAL YANG MELIBATKAN *FIRST-IN HUMAN***

APPENDIX D ADDITIONAL INFORMATION FOR FIRST-IN HUMAN CLINICAL TRIAL

**PART 1 PRECLINICAL DATA**

Please complete Appendix D for primary IP. If the trial is performed with several IPs, please complete Appendix D for each IP.

|  |  |  |
| --- | --- | --- |
|  | Evidence of previous exposure of humans to compounds with related modes of action. | Yes No  If Yes, provide details |
|  | Evidence from animal models for potential risk of serious toxicity.  Please provide details for:   1. Single and Repeat dose toxicity 2. Genotoxicity in vitro and in vivo 3. Phototoxicity 4. Other relevant toxicity study | Yes No |
|  | Evidence of a risk analysis of the preclinical data for the IPs, including:   1. Identification of on-target and off-target areas of the IPs 2. The adverse events associated with on-target and off-target areas 3. Relevance of the animal model 4. Justification of safe starting dose 5. Justification of maximum administered dose/exposure 6. Justification of multiple dose (if applicable) |  |
|  | Preclinical toxicities that will be actively monitored in the First-in Human Clinical Trial and the intensity of monitoring |  |

**PART 2 DESCRIPTION OF IP ADMINISTRATION**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **3.18** | Route of administration |  | |
| 1. **3.19** | Rate of administration (for IV only) |  | |
| 1. **3.20** | Estimation of first dose in human |  | |
| 1. **3.21** | Expected total exposure of the associated drug and the anticipated plasma concentrations in human |  | |
| 1. **3.22** | Comparison of above value in **(D)** against the exposure and achieved concentrations in the non-clinical studies |  | |
| 1. **3.23** | The dose escalation strategy with justification (if applicable) |  | |
| 1. **3.25** | Application of sentinel dosing in trial design  Period of observation of the first subject prior to the subsequent doses with justification | | yes  no |
| 1. **3.26** | Period of observation between first subject administration of IP to subsequent subjects within the cohort | |  |
| 1. **3.27** | Stopping Rules | |  |