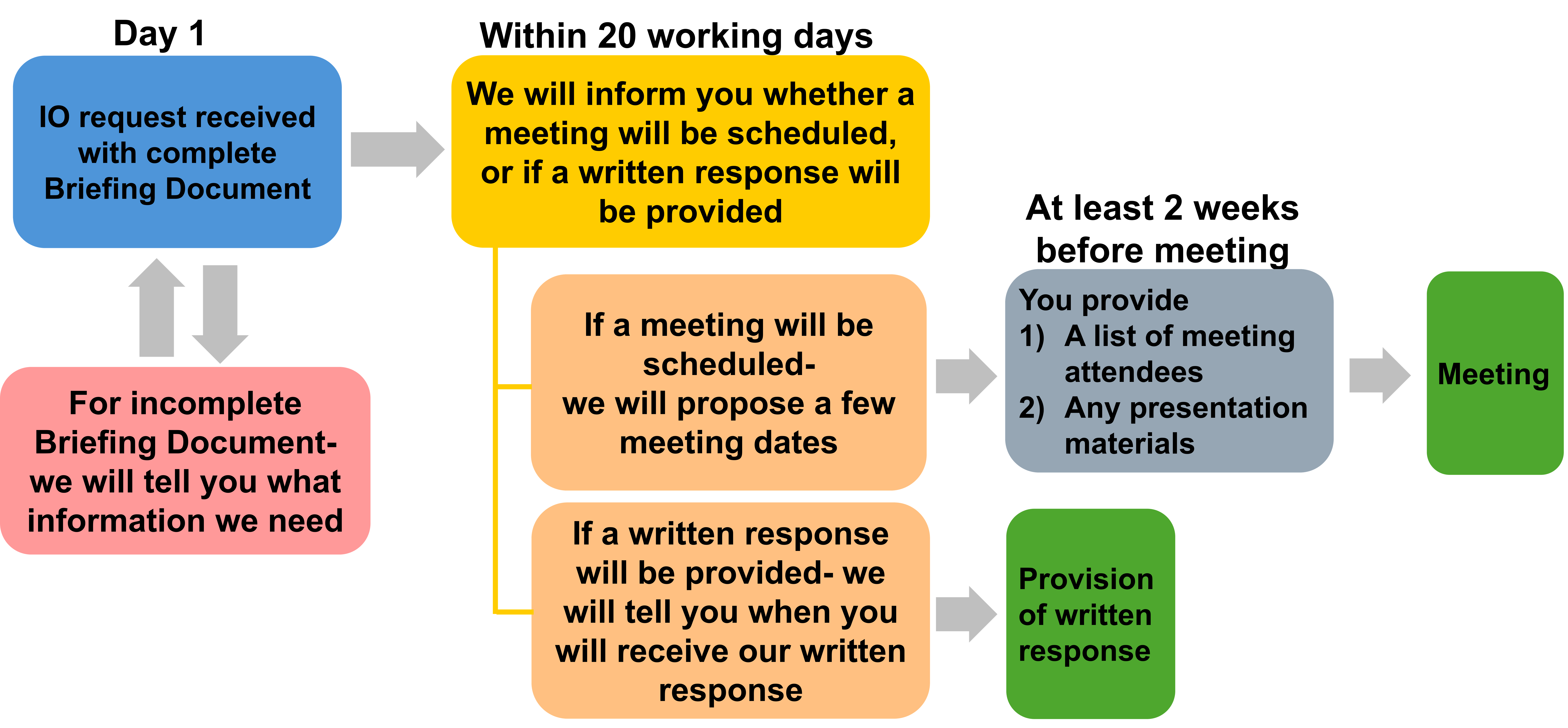
This form should be used to request a meeting with the Innovation Office (IO), Health Sciences Authority. Please complete this form and send it with your Briefing Document to [HSA\_InnovationOffice@hsa.gov.sg](mailto:HSA_InnovationOffice@hsa.gov.sg).

You may seek scientific and/or regulatory advice on novel investigational products that are either Therapeutic Products (TPs) or Class 2 Cell, Tissue and Gene Therapy Products (CTGTPs) at any stage of your product development.

Once you have submitted your request, we will inform you within 20 working days of receiving a complete Briefing Document whether a meeting will be scheduled, or if a written response will be provided. This decision will be based on the complexity of your questions. If your request may benefit from further discussion, we may propose a meeting to discuss the details of your request in depth. The 20-day timeframe is for us to inform you whether a meeting will be arranged, or if not needed, the estimated timeline for receiving HSA’s written response. A meeting will not be scheduled during this period.

For more information, please visit the Innovation Office webpage on HSA website:

<http://www.hsa.gov.sg/clinical-trials/innovation-office>



**Before requesting a meeting with us…**

You should review HSA’s Guidance on submission of Innovation Office requests, which includes guidance on how to prepare your list of questions and your Briefing Document. You may also refer to the following additional regulatory guidance documents for TPs and CTGTPs before requesting a meeting with HSA.

General HSA Guidance Documents

(<http://www.hsa.gov.sg/clinical-trials/regulatory-guidances>)

* Guidance on submission of Innovation Office requests
* Guidance on regulatory requirements for new applications and subsequent submissions

**Guidelines relevant for Therapeutic Products**

Non-Clinical Guidelines

* ICH M3(R2) and Q&As(R2): Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals
* ICH S6(R1): Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
* ICH S9: Nonclinical Evaluation for Anticancer Pharmaceuticals

Clinical Guidelines (For First-In-Human Clinical Trials)

* EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products
* FDA Guidance: Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers

Chemistry, Manufacturing and Controls (CMC) Guidelines

* EMA Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials
* EMA Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials

**Guidelines relevant for Cell, Tissue and Gene Therapy Products**

HSA Guidance Documents

* HSA Guidance on the chemistry, manufacturing and controls requirements for cell, tissue or gene therapy products for clinical trials and product registration ([Appendix 8 of the CTGTP registration guide](http://www.hsa.gov.sg/docs/default-source/hprg-atpb/appendices/appendix-8-chemistry-manufacturing-and-controls-requirements-for-cell-tissue-or-gene-therapy-product-for-clinical-trials-and-product-registration.pdf?sfvrsn=c4ac1689_2))

Other Regulatory Guidelines

* EMA Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials
* Food and Drug Administration (FDA) guidance: Preclinical Assessment of Investigational Cellular and Gene Therapy Products
* FDA Guidance:  Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)
* FDA Guidance: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products
* FDA Guidance: Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products
* FDA Guidance: Human Gene Therapy Products Incorporating Human Genome Editing

**Tell us about you**

|  |  |
| --- | --- |
| Company/organisation name |  |
| Company/organisation contact person |  |
| Collaborator(s) (e.g., clinical investigator, contract manufacturer) | 1.  2.  3. |

**Tell us about your product**

|  |  |
| --- | --- |
| Product name/description |  |
| Type of product | Chemical/small molecule  Biologic  Cells, tissue, and gene therapy product |
| Mechanism of action |  |
| Proposed indication / Target patient population |  |
| Dosage form |  |
| Route of administration |  |
| Stage of development | Preclinical development  Clinical development  Others (please specify): |
| Do you intend to conduct clinical trials or register your product in Singapore? | Yes  No  We prioritise requests from companies intending to develop or register their product in Singapore. |
| Have you sought advice on this development programme from other regulatory authorities (e.g., FDA, EMA, MHRA)? | Yes  No  If ‘Yes’, please provide details and attach all advice received. |

**How can we help**

|  |  |
| --- | --- |
| Scope of IO consultation  (you may select more than 1 category) | Nonclinical  Clinical  Chemistry, manufacturing and controls (CMC)  Manufacturing  Others (please specify):  Please provide details of your questions below. |

**List of specific questions for HSA**

Please group your questions by disciplines (e.g., Nonclinical, Clinical, CMC, Manufacturing). Your questions should ideally be posed in a such a way that we can either agree or disagree with a proposed plan. **Please refer to the HSA Guidance on Submission of IO Requests, Section 3, for examples of clear and focused questions.**

1.

2.

3.

**Your Briefing Document**

**Please submit this as a separate document.**

Your Briefing Document should include adequate background information and product description. In addition, supporting information relevant to your questions should be included. Your Briefing Document should be structured, well-organised, and paginated with relevant information presented in a manner for easy reference, and ideally accompanied by a table of contents. Please refrain from submitting separate publications as the Briefing Document; instead, summarise in the Briefing Document the pertinent and specific aspects from the publications that are relevant to the context of the questions asked. **Please refer to the HSA Guidance on Submission of IO Requests, Section 4, for examples of supporting information that may be included in the Briefing Document.**