|  |  |
| --- | --- |
| **Application Number*** NDA/BLA number or preassigned NDA/BLA number (if applicable)
* IND number
 |   |
| **Sponsor** |  |
| **Product Name**  |  |
| **Review Division** |  |
| **Request Date** |  |
| **Topline efficacy and safety results** | **Attach summary of topline results (maximum two pages)** |

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| --- | --- | --- | --- | --- |
| **Country** | **Application Type** (\*NME/NAS/BLA or supplement)  | **Proposed Indication** | **Proposed final (complete) dossier filing date:** (mm/dd/yyyy) | **Contact information for Sponsor or Sponsor-affiliate responsible for submission (name, address, phone number, email address, contact person)** |
| **USA** |  |  |  |  |
| **Australia** |  |  |  |  |
| **Brazil** |  |  |  |  |
| **Canada** |  |  |  |  |
| **Israel** |  |  |  |  |
| **Singapore** |  |  |  |  |
| **Switzerland** |  |  |  |  |
| **United Kingdom** |  |  |  |  |

\*NME/NAS: New Molecular Entity/New Active Substance

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| --- | --- | --- | --- | --- |
| **Country** | 1. **If you are not submitting to a certain POP(s) please provide the rationale.**
 | **Proposed Approval Pathway(s) and Timeline (Standard/Priority)** | **Clinical Trials Supporting Proposed Indication** | **Other relevant information (e.g., PIP or Orphan designation, NAS used with medical device, break through therapy designation, fast track designation, rolling review or real-time oncology review etc.)** |
| 1. **If you are not submitting to a certain POP(s) would you reconsider if they were interested in participating?**
 |
| **USA** | a) |  |  |  |
| b) |
| **Australia** | a) |  |  |  |
| b) |
| **Brazil** | a) |  |  |  |
| b) |
| **Canada** | a) |  |  |  |
| b) |
| **Israel** | a) |  |  |  |
| b) |
| **Singapore** | a) |  |  |  |
| b) |
| **Switzerland** | a) |  |  |  |
| b) |
| **United Kingdom** | a) |  |  |  |
| b) |