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| --- | --- | --- | --- | --- | --- |
| **Risk assessment of the IMP(s) (to be completed by the Principal Investigator)**  **Categorisation of the Phase I trial** | | | | | |
| **Study Title:** |  | | | | |
| **Sponsor:** |  | | | | |
| **R&D Number:** |  | **PI:** |  | | |
|  | | | | Yes | No |
| 1. According to the approved protocol and IB, has the IMP been administered to humans anywhere in the world? No – category 4; yes Q2 | | | |  |  |
| 1. Are the IMP/combination of IMP(s) licensed product(s) being administered at or below their licensed dose by their licensed route & formulation (but not necessarily in its licensed indication)? Yes – category 1; No Q3 | | | |  |  |
| 1. Is the IMP an unlicensed product being administered as a monotherapy at a dose and by a route and formulation established in another trial? Yes – category 2; No Q4 | | | |  |  |
| 1. Is the IMP an unlicensed product being administered as monotherapy at a different dose or route, but in the same formulation to that used in another trial? Yes – category 2; No Q5 | | | |  |  |
| 1. Is the IMP an unlicensed product being administered in combination with a licensed product or standard care regimen? Yes – Q5a-d 2; No Q6 | | | |  |  |
| * 1. Is the licensed or standard care regimen dose & route unchanged/not exceeded? | | | |  |  |
| * 1. Is the IMP an unlicensed product being administered at or below a dose established in another trial? | | | |  |  |
| * 1. Is the IMP unchanged (in route of administration and formulation) from that established in another trial? | | | |  |  |
| * 1. Has the combination been administered to humans prior to this study? | | | |  |  |
| All Yes – category 2; any No: Category 3 | | | |  |  |
| 1. Are there 2 or more IMPs both / all of which are being administered outside their monotherapy / combination standard or licensed indications?? Yes – Q6a-c 2; No - individual assessment of study | | | |  |  |
| * 1. Are the products being administered in combination at or below individual drug doses established in other trials? | | | |  |  |
| * 1. Has the combination been administered to humans prior to this study? | | | |  |  |
| * 1. Is the route of administration and formulation unchanged from that used in another trial? | | | |  |  |
| All Yes – category 2; any No: Category 3 | | | | | |

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| **Risk rating of Phase I trial** |
| Please indicate the category below:  **Risk rating of IMP(s)**  1 🞏No real risk from a safety perspective – all drugs are ‘standard of care’ in another setting.  2 🞏 No element of first time in human.  3 🞏 First time in human, but low risk of unexpected toxicity or no element of first in human but unknown toxicity.  4 🞏 First time in human and unknown risk of toxicity.  **Please complete the rest of this form and submit to the FIH Phase I committee if category 3 or 4 only. If category 1 or 2, no submission to the FIH Phase I committee is required.** |

**Please Complete**

|  |  |  |
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| **Principle Investigator** | Name: | Date: |
| Signature |  |
| **Phase I FIH Cancer Trials** | | |
| **Chair of CTEC Confirmation of Risk Rating** | Name: | Date: |
| Signature: |  |

**Trials where Risk has been Recategorised**

|  |  |  |
| --- | --- | --- |
| **Reason for Recategorising:** | | |
|  | | |
| **Chair of Phase I FIH Committee** | Name | Date |
| Signature |  |