This template may be used by Sponsors of clinical trials as part of the application dossier.

EU CT number : …………………………………………………………………………………………………………………

A separate document should be completed and submitted for each site.

This template has been developed and endorsed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No. 536/2014 Clinical Trials on Medicinal Products for Human Use.

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| **Personal Information** | |
| **Name:** | Click or tap here to enter text. |
| **Title:** | Click or tap here to enter text. |
| **Profession:** | Click or tap here to enter text. |
| **Current position:** | Click or tap here to enter text. |

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| **Professional Registration[[1]](#endnote-1)** | |
| **Registration number:** | Click or tap here to enter text. |
| **Registration body:** | Click or tap here to enter text. |
| **Registration expiry date (if applicable):** | Click or tap here to enter text. |
| **Registration state/province (if applicable):** | Click or tap here to enter text. |

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| **Education and Qualifications[[2]](#endnote-2)** | | |
| **Institution name** | **Qualification** | **Year** |
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| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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| **Current employment** | |
| **Institution name:** | Click or tap here to enter text. |
| **Department:** | Click or tap here to enter text. |
| **Institution address:** | Click or tap here to enter text. |
| **Telephone number:** | Click or tap here to enter text. |
| **E-mail address:** | Click or tap here to enter text. |

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| --- | --- | --- | --- |
| **Professional experience[[3]](#endnote-3)** | | | |
| **Position** | **Institution name and department** | **Start year** | **End year** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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| **Relevant clinical trial/study experience[[4]](#endnote-4)** | | | | | |
| **Investigator role** | **Therapeutic area** | **Type of trial** | **Year started** | **Phase** | **Ongoing** |
| Choose an item. | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Choose an item. | Choose an item. |
| Choose an item. | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | Choose an item. | Choose an item. |
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| **Training** | | |
| **Research training (including GCP)** | **Institution name** | **Year obtained** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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| --- | --- |
| **Date completed[[5]](#endnote-5):** | Click or tap to enter a date. |
|  | Click or tap here to enter text. |

1. As per national legislation [↑](#endnote-ref-1)
2. Relevant to be an investigator [↑](#endnote-ref-2)
3. This should cover the preceding 10 years as a maximum [↑](#endnote-ref-3)
4. Idem [↑](#endnote-ref-4)
5. The CTR does not require signing individual documents in the clinical trial application – a request for signature could however be subject to national legislation. [↑](#endnote-ref-5)