This template may be used by Sponsors of clinical trials as part of the application dossier. 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. However, this template is also relevant under Directive 2001/20/EC and may be used in advance of the Regulation applying.

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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]](#footnote-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]](#footnote-2)** | | |
| **Institution name** | **Qualification** | **Year** |
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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]](#footnote-3)** | | | |
| **Position** | **Institution name and department** | **Start year** | **End year** |
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| **Relevant clinical trial/study experience[[4]](#footnote-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:** | Click or tap to enter a date. |
| **Signature[[5]](#footnote-5):** | Click or tap here to enter text. |

This addendum describes the specific Clinical trial/study experience **relevant** for the CTA with EudraCT number:

Click or tap here to enter EudraCT number.

|  |
| --- |
| **Clinical trial/study experience relevant for the submitted CTA[[6]](#footnote-6)** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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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| --- | --- | --- |
| **If applicable: Other technical experience relevant for the submitted CTA** | | |
| **Institution name** | **Technical expertise** | **Year(s)** |
| 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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1. As per national legislation (RIZIV-INAMI number) [↑](#footnote-ref-1)
2. Relevant to be an investigator [↑](#footnote-ref-2)
3. This should cover the preceding 10 years as a maximum [↑](#footnote-ref-3)
4. This should cover the preceding 10 years as a maximum [↑](#footnote-ref-4)
5. As per national legislation, a signed version of the CV should be included in the trial master file however a signed version may not be required for regulatory review, this should be confirmed nationally.   
   **In Belgium**, a signed version is needed for review by the Ethics committee [↑](#footnote-ref-5)
6. This should cover the preceding 10 years as a maximum [↑](#footnote-ref-6)