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| **Project identification** |
| Project name/description |  |
| Investigator |  |
| Trial site |  |
| Sponsor's representative |  |
| Identification in continuous record of project activities  |  |

**Description of qualifications required by investigator and project team members in order to conduct the trial** (e.g. medical specialty, training in the use of special testing or IT equipment)

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**Description of facilities and equipment necessary to conduct the trial**
(e.g. measuring equipment, software, premises, storage facilities for documents/medicinal products)

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 **Description of necessary support functions, including project team members**
(e.g. data handler, statistician, laboratory personnel, pharmacy personnel)

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**Description of partners and environments necessary to complete the trial**

(e.g. health enterprise, hospital, medical practice or other health institution)

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**Plan for recruiting trial subjects**

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 **Plan for regulatory storage of medicinal products**

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**Plan for regulatory archiving and storage of the project documentation, including personal data**

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Date dd.mm.yyyy Signature (Sponsor's representative)