# Form to apply for authorisation of clinical trials falling under the risk-adapted assessment of already marketed medicinal products under the licensed indication (Type A trials)

**Protocol title:**

**EudraCT number:**

**Investigational medicinal products:**

This application is covered by the risk-adapted assessment as my trial satisfies the following criteria:

* The investigational medicinal product\* is used under the licensed indication (licensed indication is described in the [summary of product characteristics](http://laegemiddelstyrelsen.dk/en/service-menu/product-information/summaries-of-product-characteristics)).
* The investigational medicinal product is used under the licensed dose and route of administration as described in the summary of product characteristics.
* The investigational medicinal product is used alone or in well-described (dose, route of administration, duration) and known combinations with other medicinal products.
* The investigational medicinal product is used in the licensed patient population as described in the summary of product characteristics.
* The risk involved for the trial participants is on the same level as the risk of standard treatment.
* A placebo is not used in the trial.

If the trial is testing an investigational medicinal product which is not marketed in Denmark, but in another EU member state, it is important to document that the trial site has experience in using the medicinal product. Such experience could be if the site has used the investigational medicinal product via a [compassionate use permit](http://laegemiddelstyrelsen.dk/en/topics/authorisation-and-supervision/compassionate-use-permits).

**Please describe how the trial treatment distinguishes itself from usual clinical practice:**

**Please indicate the date when the trial is expected to end (last patient, last visit)**

**List of appendices (see checklist - please pay attention to the checklist's notes)**

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| --- | --- | --- |
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| **Date** |  | **Signature** |

\*Investigational medicinal products: A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or to gain further information about the authorised form.