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**Clinical Trial Title :** « Multicentre, non-randomised, open-label, single agent phase II study to determine the clinical benefit of trastuzumab emtansine (T-DM1) in HER2-positive metastatic breast cancer patients with brain metastasis »

**EudraCT Number :** « 2016-004398-41 »

**Protocol Number :** « IJB-BC-TDM1BM-2016 »

**Study name :** « KIARA »

**NO or PARTIAL RESULTS FOR THIS TRIAL**

**(I) Accrual**

- ☒ The trial is terminated before any subject was recruited.
- ☐ The trial is terminated whereas \_\_\_\_\_ subjects/ \_\_\_\_\_ were recruited.

**(II) Reasons**

- ☐ The positive opinion by the Ethics Committee in charge of the trial is not granted or is irrevocably revoked.
- ☐ The authorisation by the Competent Authority of the Member State concerned in charge of the trial is not granted or is irrevocably revoked.
- ☐ The sponsor became or was declared insolvent or a petition in bankruptcy has been filed against it or it is dissolved.
- ☐ Early end of the scientific collaboration with one or more partners.
- ☐ Early termination due to safety.
- ☐ Discontinuation or change of the strategic direction of the development of the medicinal product(s) that the sponsor wanted to study.
- ☒ Trial logistics or limited trial population, as defined by the inclusion/exclusion criteria, leading to a poor recruitment.
- ☐ Publication of other clinical trials which changed the therapeutic landscape and rendered our trial design obsolete.
- ☐ Publication of other clinical trials already demonstrating the clinical interest of our trial and rendered our trial obsolete.

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Institut Jules Bordet, Association Hospitalière de Bruxelles régie par la loi du 8 juillet 1976  
Jules Bordet Instituut, Ziekenhuisvereniging van Brussel onderworpen aan de wet van 8 juli 1976