

## Unreported metastatic breast cancer clinical trials in Germany: Sponsor responses

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Original study protocol here: <https://osf.io/qc7xm>

Responses received between late 2022 and early 2023.

### **Abbvie: NCT04274933; 2019-003452-36**

The trial (NCT04274933) did not enroll any patients in Germany and was ultimately terminated. At study termination, the proper regulatory authorities were informed of our decision.

### **Merrimack Pharmaceuticals: NCT02213744; 2014-003159-73**

As you might be aware from our website, Merrimack Pharmaceutical ceased all Research and Development efforts in 2019, and no longer employs any research or clinical scientists, or any full time employees at all. We made every effort to publish and disclose all clinical trial data for our various drugs prior to shutting down operations that year or at a minimum make sure the data was made available to the lead clinical investigators. However, this trial was not ongoing during the final year of operations and appears to have been missed from the effort at the time. This Phase II trial was stopped early by the safety data monitoring board at the time and a clinical study report was generated. We have located both the report and a draft publication based on that report that only requires an introduction and discussion to be finalized. We agree with ensuring access to trial data, and appreciate you bringing this to our attention. We will work with the clinical/academic PIs on the project to help see they have everything they need to publish the full clinical study data in 2023.

### **Technical University Munich: NCT02276300; 2010-018538-33\***

The study could not be conducted as originally planned due to the difficulty in recruiting suitable patients. Only two patients with breast carcinoma were available for the clinical trial. It was therefore cancelled. The small number of participants also precluded publication in journals.

The report on the results of the clinical trial (EudraCT no. 2010-018538-33) was submitted to the Paul Ehrlich Institute via the PharmNet.Bund portal in due time one year after the trial was discontinued. As this is a phase I clinical trial, it was not released to the public in accordance with regulatory requirements.

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*Die Studie konnte aufgrund der Schwierigkeit, passende Patientinnen zu rekrutieren, nicht wie ursprünglich geplant durchgeführt werden. Für die Klinische Prüfung standen uns lediglich zwei Patientinnen mit Mammakarzinom zur Verfügung. Sie wurde deshalb abgebrochen. Die geringe Anzahl an Teilnehmerinnen schloss auch eine Veröffentlichung in Journals aus.*

*Der Ergebnisbericht der Klinischen Prüfung (EudraCT-Nr. 2010-018538-33) wurde fristgerecht ein Jahr nach Abbruch beim Paul-Ehrlich-Institut über das Portal PharmNet.Bund eingereicht. Da es sich hier um eine Klinische Prüfung der Phase I handelt, wurde diese gemäß den behördlichen Bestimmungen nicht für die Öffentlichkeit freigeschaltet. [original text]*

*\*Note: We were unable to find a public record for 2010-018538-33, possibly because this was a Phase I trial subject to EMA /EUCTR confidentiality safeguards.*

## Universitätsklinikum Magdeburg: DRKS00014139

There is no primary completion date because the study could not be completed. For various reasons, only very few patients could be included and the study was terminated prematurely. With an insufficient number of pat[ients], there was also no publication (no sufficient statistical evaluation possible). It would therefore not be correct to use the term "unpublished", as there were no results in the sense of the research question that could have been published.

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*Es gibt kein primary completion date, da die Studie nicht komplettiert werden konnte. Aus verschiedenen Gründen konnten nur sehr wenige PatientInnen eingeschlossen werden und die Studie wurde vorzeitig beendet. Bei nicht ausreichender Anzahl an Pat[ienten] gab es auch keine Publikation (keine suffiziente statistische Auswertung möglich). Es wäre deshalb nicht richtig, den Begriff "unveröffentlicht" zu nutzen, da es keine Ergebnisse im Sinne der Fragestellung gibt, die man veröffentlichen hätte können. [original text]*

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