

Blood cancer clinical trials Long-term follow-up using Integrated healthcare SystemS data (BLISS): a study protocol for a data linkage study

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Background

- Clinical trials are gold standard in evidence-based medicine.
- Most clinical trial follow-up is through clinic attendance and trial-specific data collection.
- There is often overlap between trial collected data and data already recorded and collected routinely in clinical practice, (e.g. electronic health records or disease registries).
- Using routinely collected healthcare systems data (HSD) could reduce cost, time and resources needed to ascertain clinical trial outcomes.
- Key concerns of using HSD for trial follow-up are data quality, accuracy, and reliability.
- Evidence is needed that HSD are reported to an equivalent standard to trial-specific collected data for trial outcomes.

Objectives

The BLISS platform will link multiple myeloma clinical trials with national HSD to create a research database.

The database will be used to evaluate the quality and accuracy of HSD for use in determining clinical trial endpoints and conducting further clinical research.

Objectives are show in **Figure 1**.

Mortality

Evaluating routinely collected mortality data to estimate long-term overall survival across myeloma clinical trials.

Data Utility Comparisons

Assess the quality and reliability of HSD in comparison to trial-specific collected data for a range of outcomes.

Diversity

Examining diversity and representativeness in trial participants and equity of outcomes.

Frailty

Comparing methods of defining frailty and prognostic ability of these indices.

Bone Disease

Identifying and describing bone-related treatment and outcomes.

Figure 1: BLISS objectives

Patient and Public Involvement

Patient voice represented throughout project

- Patient co-applicant on grant funding and Project Management Group
- PPI Advisory group – 6 patients, meet twice a year
- PPI representation on Project Steering Committee – 2 patients on PSC, meets once a year

Study Design and Methods

Figure 2 shows the data sets included in this data linkage project

- Approximately 5500 participants enrolled in multiple myeloma clinical trials (2008–2021).
- National HSD will be obtained from NHS England
- Data utility comparison studies will directly compare trial-specific collected data with outcomes extracted from the relevant HSD.
 - Mortality, treatment on (and after) trial including line of treatment, second cancer incidence, adverse events – infection, fracture, venous thromboembolism and cardiovascular disease
- Ethical approval was granted by the East of England – Cambridge Central Research Ethics Committee and Section 251 support from the Confidential Advisory Committee.
- Initial analyses are expected by mid-2026.

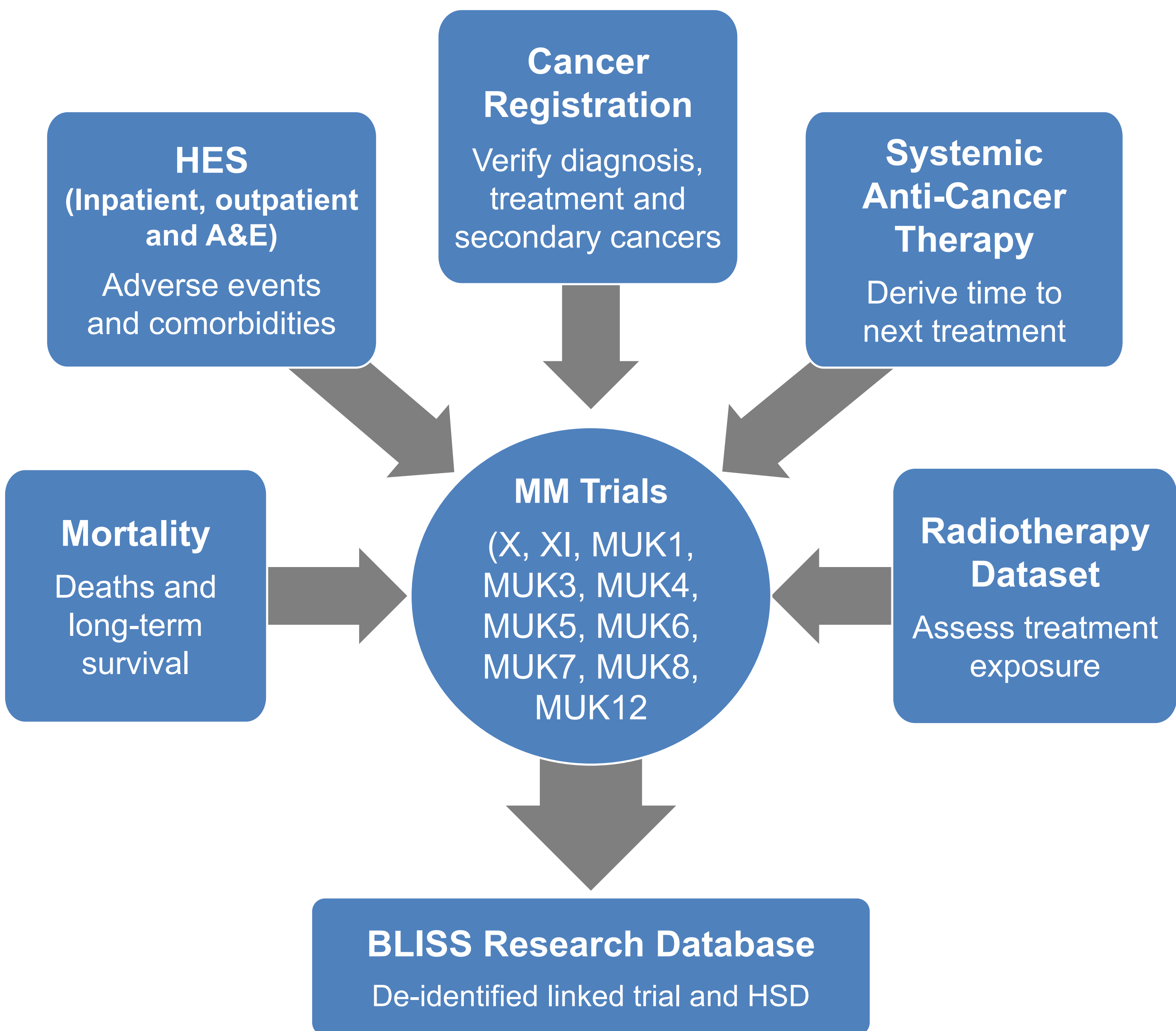


Figure 2: BLISS Data overview, HES = Hospital Episode Statistics, MM = multiple myeloma

Expected Outcomes and Impact

- The BLISS platform will provide relevant data to generate evidence required for using HSD in future clinical trials.
- Using HSD in prospective trials provides a cost-effective means for clinical trial follow-up, enabling limited research budgets to go further.

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BLISS is funded by Blood Cancer UK Transformation Research Award