BENCHISTA Project Working Group Publication Policy

Aims, summary of methods and expected main outputs

The *International Benchmarking of Childhood Cancer Survival by Stage* project, also called the *BENCHISTA Project*, is a research collaboration between multiple population-based cancer registries (PBCRs) within and outside Europe. It aims to investigate childhood cancers (CC) survival by stage between countries or larger geographic regions. Evidence will be sought for variation in tumour stage at diagnosis between jurisdictions and if this can explain any observed variation in overall survival rates between these same geographical regions.

The project focuses on six childhood solid tumours for which the PBCRs will assimilate the necessary data to assign the international consensus 'Toronto stage' at diagnosis. Where available to them, they will also collect additional data items on non-stage prognostic factors. PBCRs will share pseudo anonymised personal data to create a project database that will be processed securely under the direction of Fondazione IRCCS "Istituto Nazionale dei Tumori", Milan, Italy (INT).

The main output from this project will be the publication of two papers describing stage distribution and survival by stage for childhood cancer patients diagnosed with these six solid tumours in the time period 2014-2017. A number of tumour-specific sub-analyses are foreseen.

Collaboration and ownership of data

The BENCHISTA Project Working Group (PWG) includes representation from all PBCRs contributing data to the project, as well as tumour-specific clinical leads from the relevant European clinical trials groups, parent and patient representation, and the BENCHISTA team comprising the principal investigators at University College London (UCL) and INT, Milan, and their team members. Data are provided through a Data Controller to Data Controller relationship using processes that are compliant with the General Data Protection Regulation or similar regulations in each collaborating country.

The BENCHISTA data remain the property of the contributing registries, whose approval is required before they can be used for purposes other than those originally envisaged in the BENCHISTA protocols. All members of the Project Working Group (PWG) that provide data must be informed of any analysis being proposed and carried out.

The project database consists of maximally de-personalised data and will be retained at INT, Milan for a maximum of 10 years from project initiation, after which it will be securely deleted unless further ethical and regulatory approval are granted for further work agreed with all the CRs participating in the project as above. Use of the project database for the specified research is under the governance of the PWG and should be according to the purposes for which ethical approval has been granted.

The project is funded by Children with Cancer UK. The research sponsor is UCL.

Analyses under BENCHISTA and other protocols

Analyses approved by the participating registries under the BENCHISTA protocol are carried out at the INT in Milan, Italy.

Geographical differences will be presented by country or, depending on sample size, by geographical region, in a similar fashion to groupings used in EUROCARE publications. This will maximise statistical robustness and will minimise the risks to data privacy. If lower group sizes/numbers of cases by country are presented, this will be revisited for data and survival analysis in the future.

Collected data will be securely stored and analysed at INT. PBCRs may request a copy of their own submitted and processed data. Aggregated data may be shared confidentially with the PWG members for their scrutiny and suggestions for further analyses for specific purposes.

Authorship

All publications (abstract, poster or paper) based on pooled data must mention the BENCHISTA Working Group among the authors (or as the author), a suitable authorship formula being: >Authors A, B, C, ... and the BENCHISTA Project Working Group, with all members listed in a footnote or appendix to the article. The PIs of this study will be included as co-authors in all publications. All authors should meet the criteria for co-authorship – see addendum.

In general, the researcher who oversees/performs the analyses and wrote the paper will be first authors in the publication. The first author proposes the co-authors before and during the preparation of the article based on the received contributions.

Proposals for additional analyses and publications are encouraged and can be proposed by any member of the Working Group or by other researchers not belonging to the Working Group, providing the analysis is presented to and agreed by the PWG before any analysis commences. All analyses will be conducted on the database at INT.

To avoid duplication of effort or the publication of inconsistent results without appropriate comments, cancer registries participating in BENCHISTA should inform the Project Management Group (PMT) of any analysis of the same data within the same time period already sent to BENCHISTA.

Outcome and publication policy

The main output from BENCHISTA will be the publication of 2 papers: Tumour stage distribution at diagnosis of CC and CC survival by stage, with assessment of the contribution of any observed variation in stage distribution to variation in overall survival, as reported in the protocol and the project submitted to Children with Cancer (CWC). Further papers, including more detailed tumour-specific papers, are envisaged according to the initial findings and the completeness of the optional data variables received to permit interrogation of other factors whose variation may influence survival rates.

The use of the BENCHISTA dataset for specific studies will be promoted.

The BENCHISTA data will be used by researchers involved directly with the study and as described in the study-approved protocol and in the BENCHISTA publication policy. Within this context, the BENCHISTA Project Management Team (PMT) will verify the validity of the proposals and their coherence with the study aims.

A review article is planned to compare routine child health surveillance practices and primary care for acute paediatric illness across the participating countries. This will review published data and work with input from paediatric clinicians in each country. These will be members of the PWG (either clinicians working with the CRs and/or the tumour-specific experts nominated by the SIOP Europe clinical trials groups).

The list of articles published, in preparation or proposed will be transmitted periodically to all the BENCHISTA PWG by PMT through e-mail message or newsletter or included in a possible BENCHISTA web site.

User involvement: while different journals require specific information, all articles should mention the valuable role of the group of Experts (coming from the SIOP Europe clinical trial group) the Patient and Public Involvement and Engagement (PPIE) group and International Advisory board (IAB) in this project.

The acknowledgement section of all publications must include the phrase: "The data used in this project have been generated during the treatment and care of patients".

Other issues

Funding: All publications are required to acknowledge the funders, Children with Cancer UK (Grant Reference: 20-329) and Associazione Italiana per la Ricerca sul Cancro (AIRC) Italy (Grant reference: IG 2020 - ID. 24933).

Ethical approvals: The study has received the approvals of UCL (Ethics Project ID Number: 19963/001, 22nd April 2021) and INT (Ethics Project ID Number: 4622359, 27th May 2021).

Publicity: The Principal Investigator should alert the Research Grants Manager at the Charity at least 14 days in advance of any articles based on the Research in time to allow consideration of the implications and wider publicity potential. The Principal Investigator must ensure that copies of proposed articles (based wholly or partly on the Research) are forwarded to the Charity when the article is accepted for publication.
For oral presentation or poster at Congress, the abstract must be circulated before the deadline for submission and the PWG must be informed of its acceptance.

Open Access: The grant includes funding for open access charges for two papers.

Dissemination: All press releases must be passed to the PMT for dissemination through websites, newsletter, institutional/association/organization web site.

Addendum for specific information on internationally recognised criteria for co-authorship:

Both Lancet and BMJ follow the International Committee of Medical Journal Editors (ICMJE) recommendations (http://www.icmje.org/icmje-recommendations.pdf).

The ICMJE recommends that authorship be based on the following 4 criteria:

a. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

b. Drafting the work or revising it critically for important intellectual content; AND

c. Final approval of the version to be published; AND

d. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.