

# An ethical analysis of risk/benefit profile in basket clinical trials provides evidence how to increase the benefits and reduce risk for trial participants.



## Do basket clinical trials in oncology increase health benefits for patients?

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### Background

#### Basket clinical trials (BCTs):

- are novel trial designs commonly used in precision oncology.
- test a therapeutic intervention for multiple cancer types simultaneously under the same study protocol (Fig.1).

Patients with different cancers recruited to BCT share specific molecular characteristics which are predictive of clinical benefit from the experimental treatment.  
Little is known about the risk/benefit ratio in BCTs.

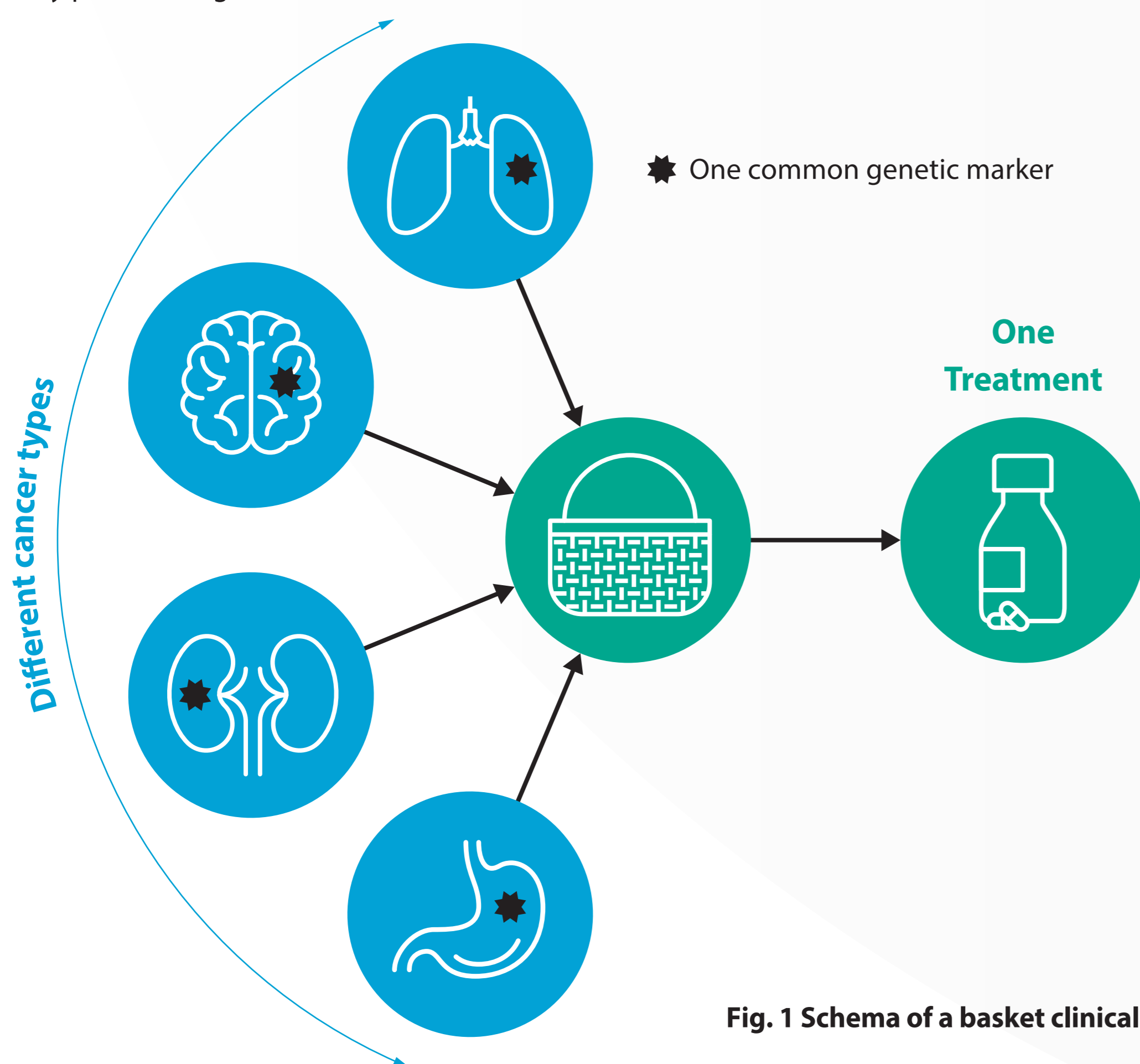


Fig. 1 Schema of a basket clinical trial

### Objectives

#### Our aims are:

- 1) to conduct a systematic review with meta-analysis to evaluate efficacy and safety profiles in BCTs in oncology.

- 2) to compare the risks and benefits for trial participants in BCTs to the risks and benefits in other oncology clinical trials with classical design.

### Methods

We systematically searched Embase, PubMed and ClinicalTrials.gov for interventional cancer BCTs published between 1 January 2001 and 14 June 2023. We will measure the risk to trial participants by evaluating treatment-related adverse events of grade 3 or higher. We will assess the benefit by analysing objective response rate, progression-free survival, and overall survival.

### Results

Of 4 722 records identified (3 413 Embase, 1 309 PubMed), we screened 423 full texts. We performed screening of conference brochures, and we reviewed references of included articles. We included 228 full texts for data extraction (Fig.2). We found 310 trials through the systematic search of ClinicalTrials.gov which we assess according to the eligibility criteria.

### Conclusion

**Our findings on the risks and benefits for trial participants in BCTs will provide a basis for discussion on clinical benefits to patients in precision oncology research.**

### Contact

**Questions? Ask me**

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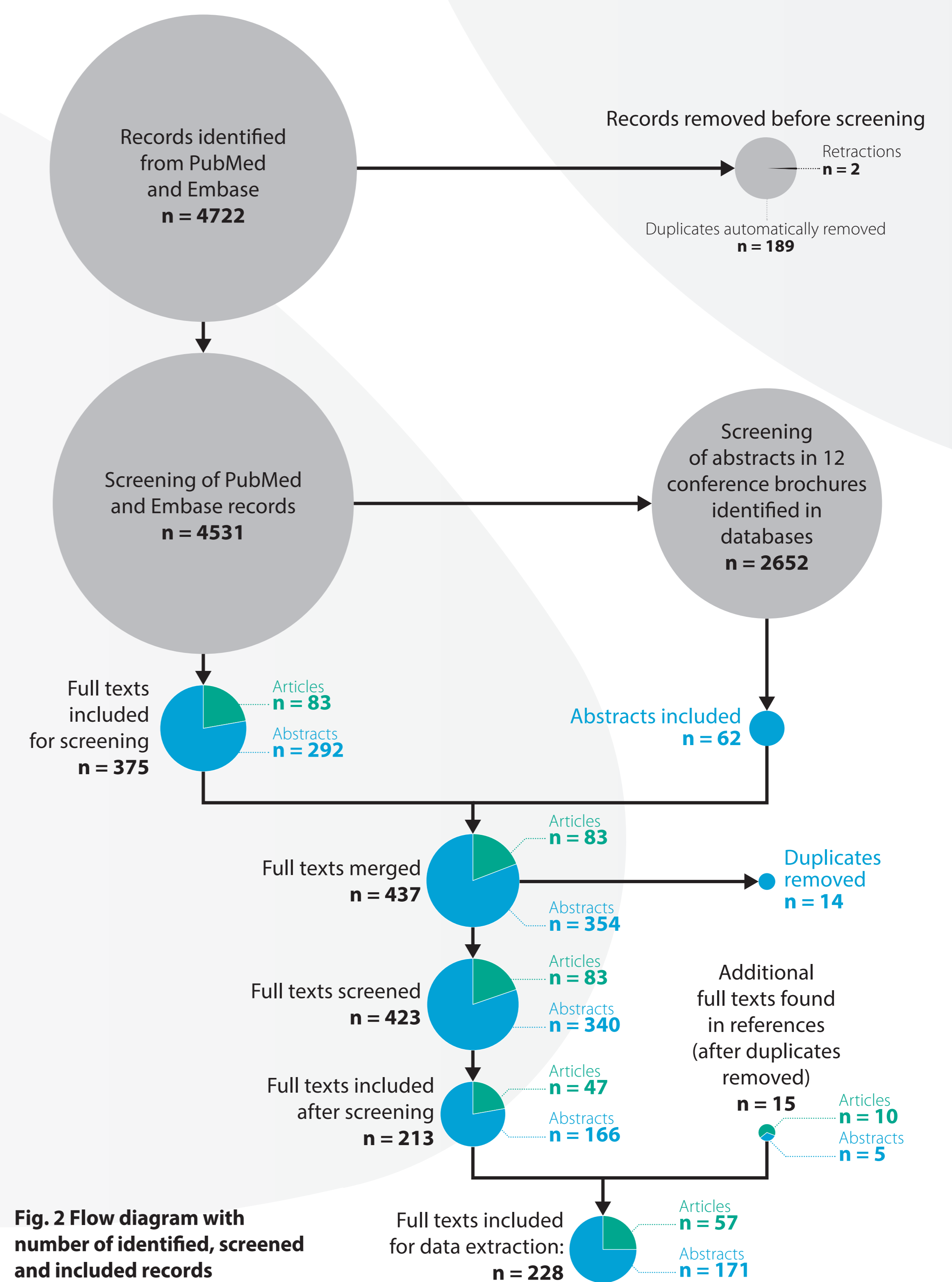


Fig. 2 Flow diagram with number of identified, screened and included records



Scan to view the study protocol