Outcome of patients participating in early phase oncology trials at the Drug Research Unit Ghent (D.R.U.G.), Belgium.

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Conflict of interest

- Employed as an investigator at the Drug Research Unit Ghent (Ghent University hospital).
- In this function I collaborated to clinical trials of various pharmaceutical companies.

Early phase oncology trials

- Phase 1 – 2a trials
  - Dose-escalation
  - Expansion cohorts

- Participants:
  - Patients with advanced oncological disease
  - Who have exhausted all treatment options
  - Who are still in good clinical condition

Research question

- What is the outcome of patients participating to early phase oncology trials ?

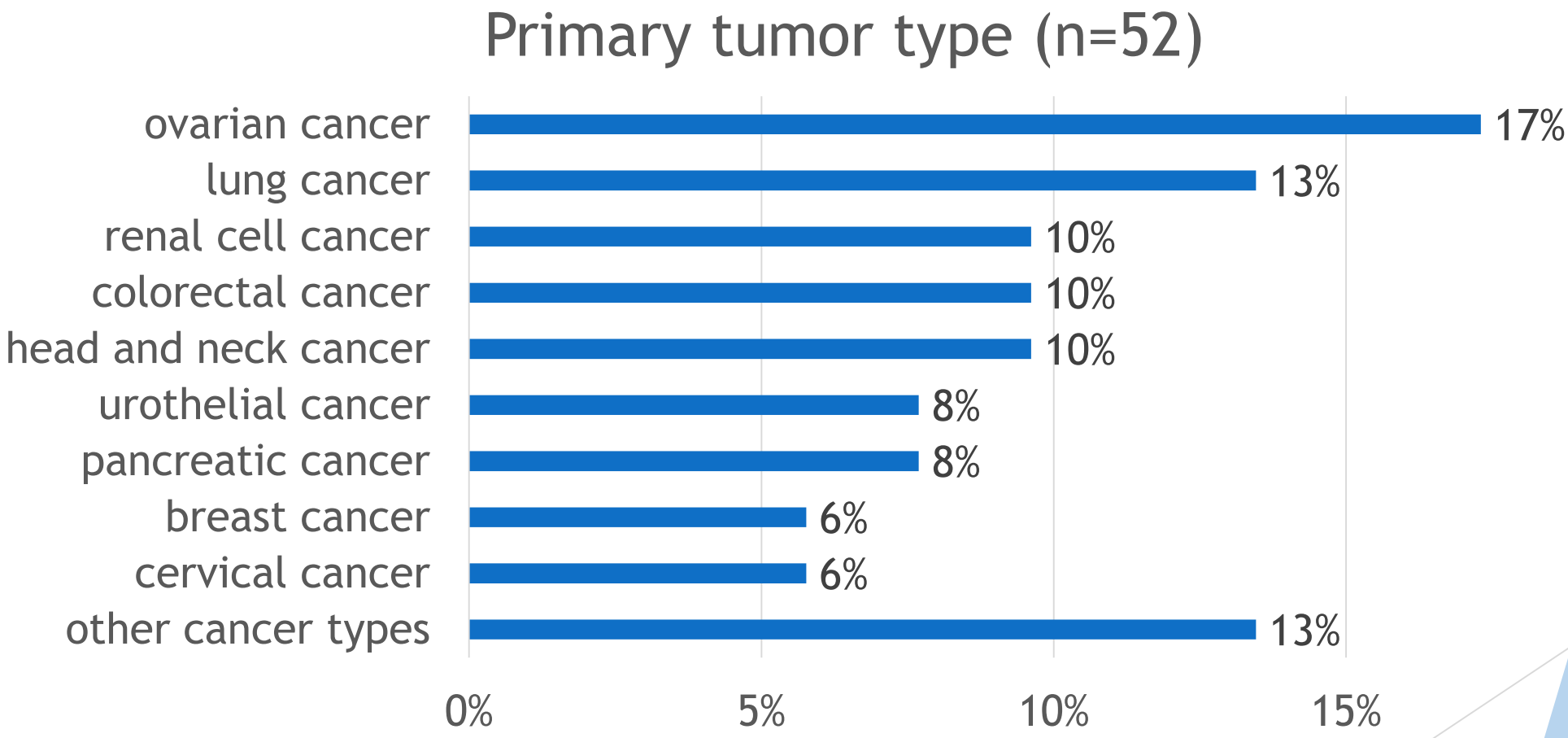
Methodology

- Analysis of data from all patients who started treatment in an early phase oncology trial between 01 Jan 2017 and 31 Jul 2018.
- Single centre (Drug Research Unit Ghent)

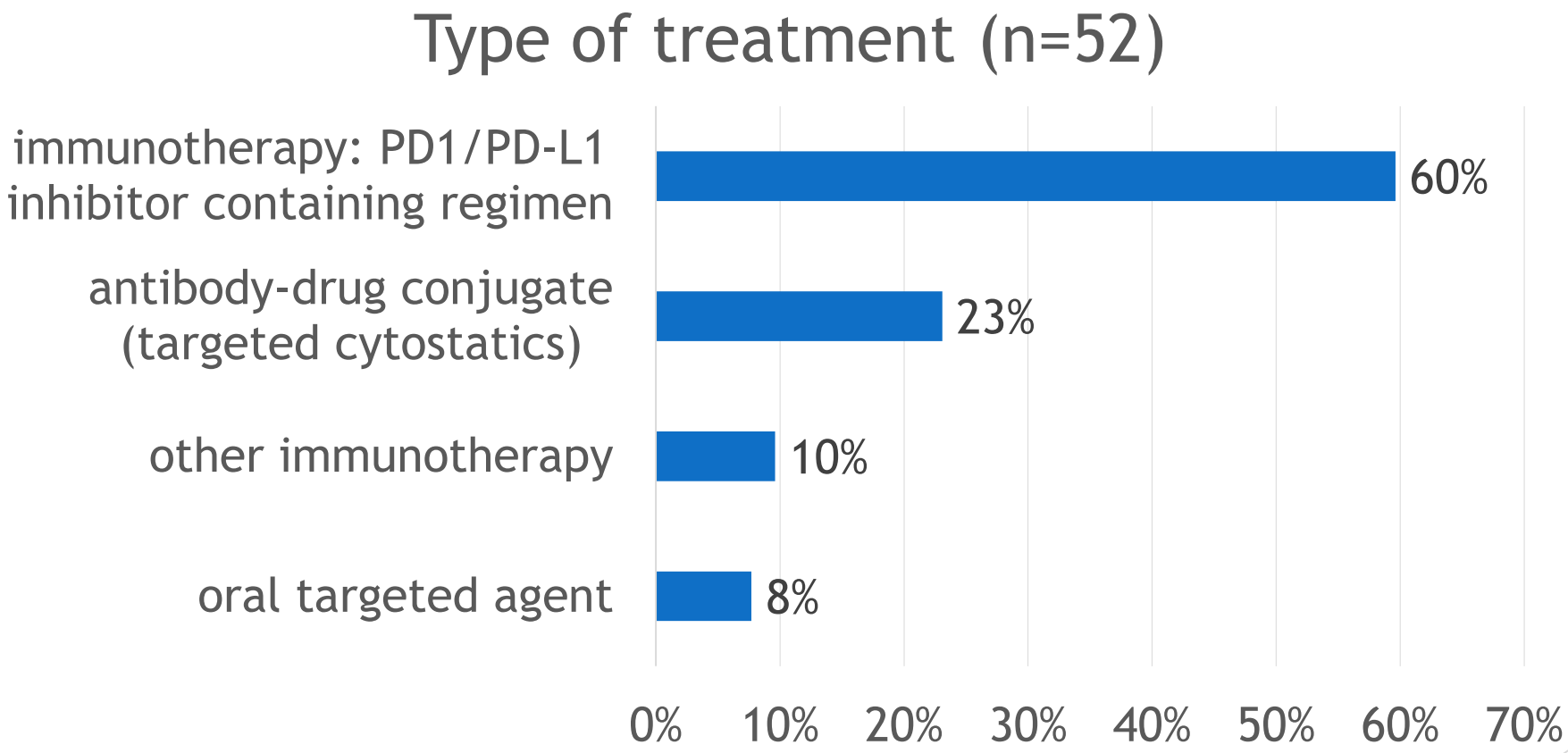
Study population (1/2)

- Start of treatment: 01 Jan 2017 - 31 Jul 2018
- Number of patients: 52
- Number of trials: 10
- Age (median, min – max): 62 years (40 – 80)
- M/F ratio: 44% - 56%
- Previous treatment lines (median, min-max): 2 (1–7)

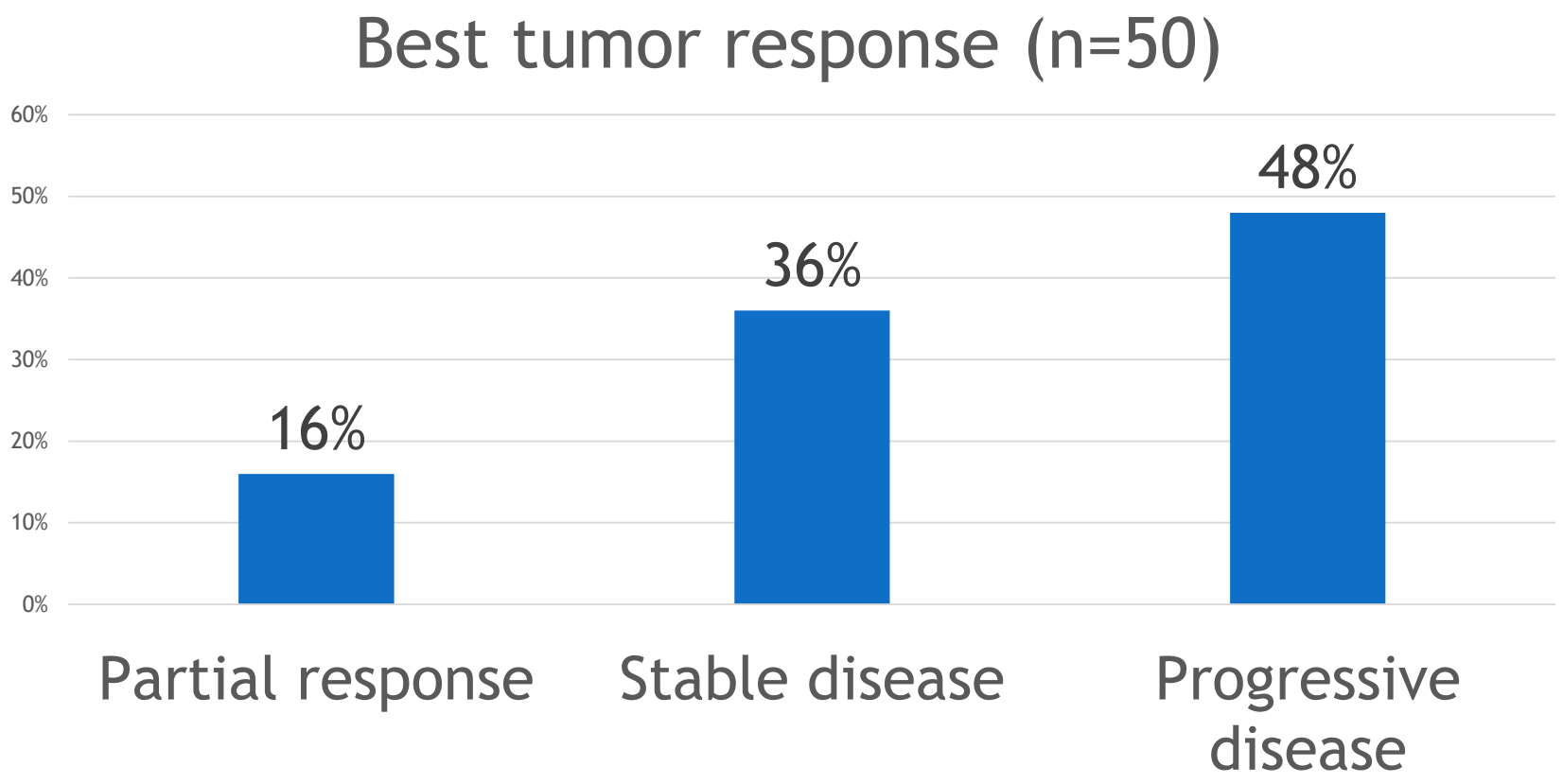
Study population (2/2)



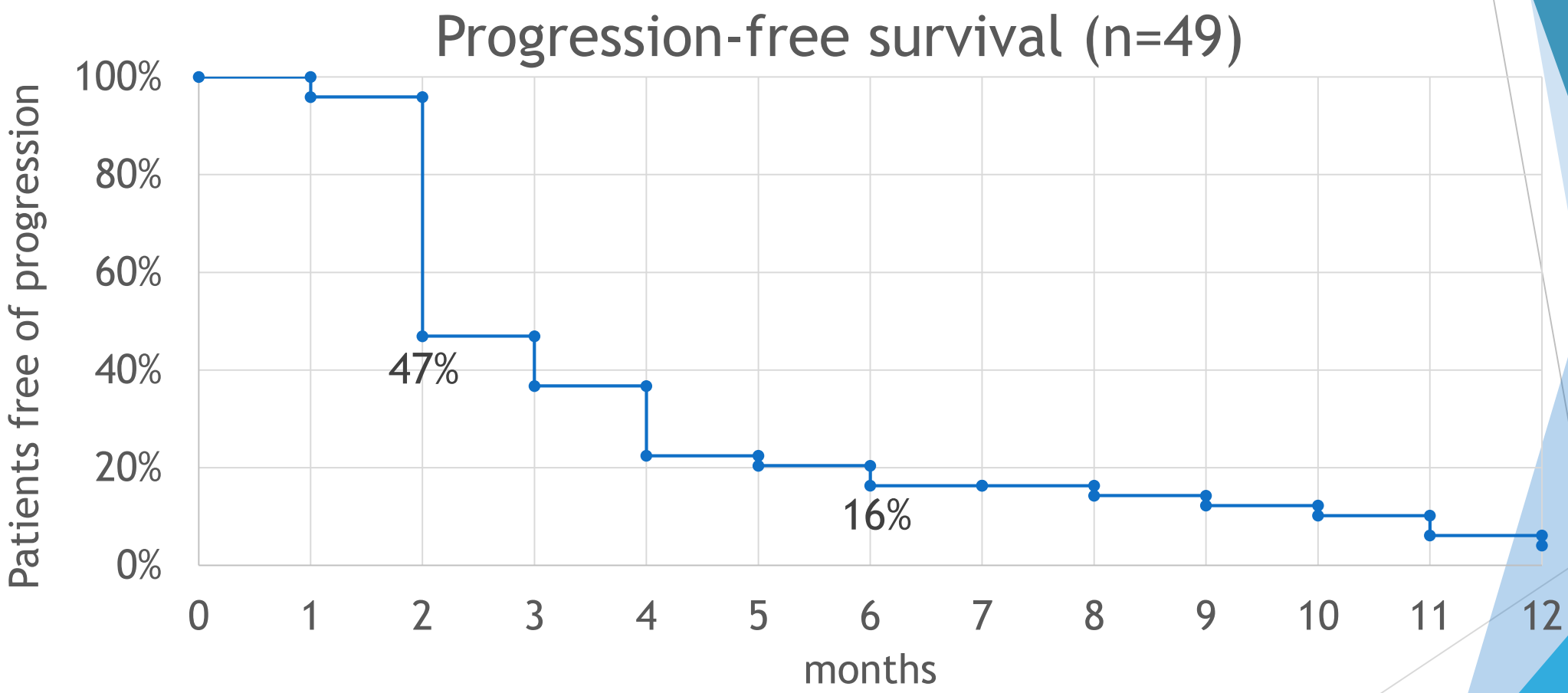
Investigational treatments



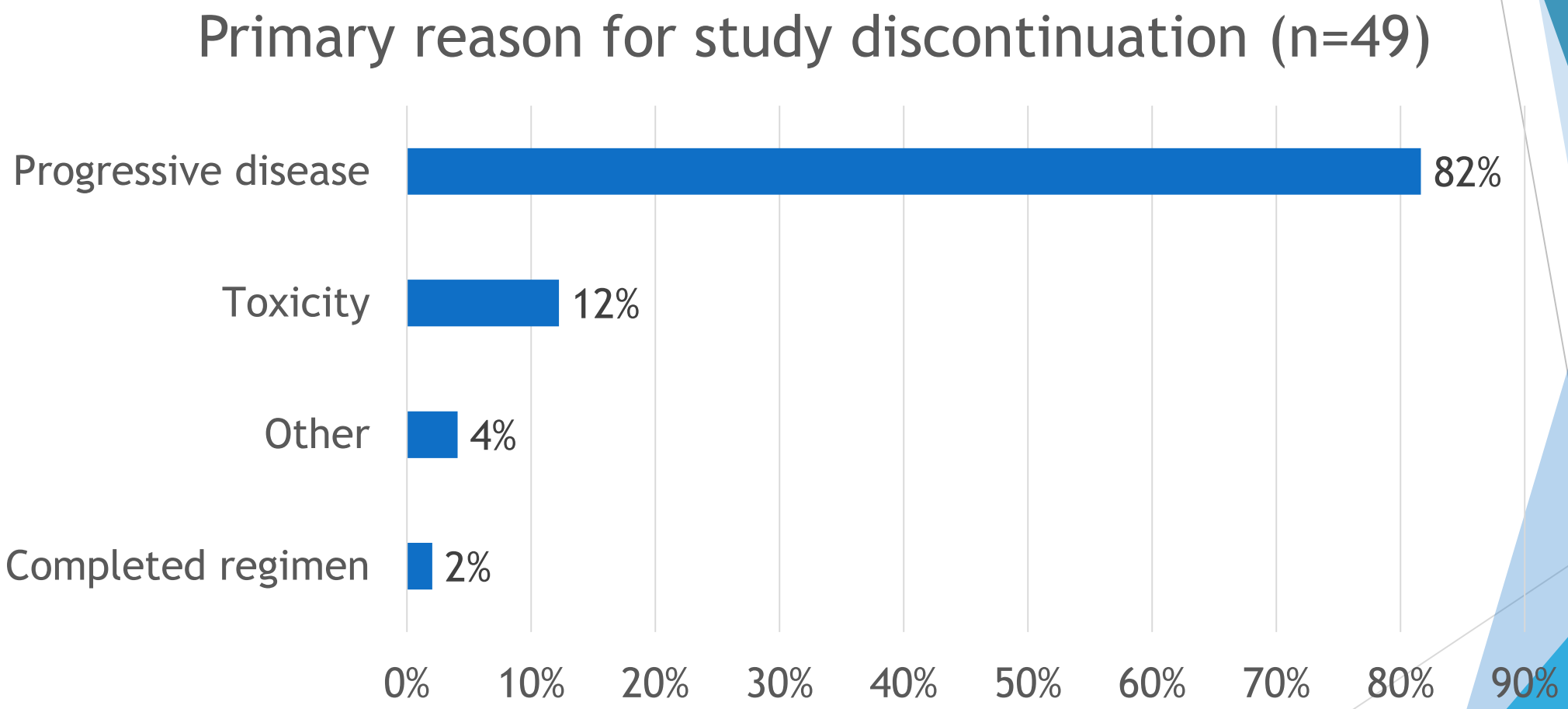
Outcome: objective response



Outcome: progression-free survival



Reasons for study discontinuation



Overview of results

- Diverse population of oncology patients
- Majority of patients received anti-PD(L)1
- Median PFS was less than 2 months, but 16% had a PFS > 6 months.

⟹ Patients participating in an early phase oncology trial have a small but realistic chance of benefit.

Response rates in the literature

Reported response rates in phase 1 oncology patients:

- Estey et al. (1986) [1947-1982]: 4,2%
- Von Hoff et al.(1991) [1970-1983]: 6%
- Horstmann et al. (2005) [1991-2002]: 10,6%
- Italiano et al. (2007) [2003-2006]: 7,2%
- Chabiba et al. (2018) [2014-2015]: 19,8%

Attempts to increase patient benefit

- Importance of patient selection
  - Several predictive models exist (e.g. RMH, GRIm, etc.)
- Biomarker selected patient populations
  - Could result in more benefit for patients participating to early phase trials

Limitations

- Single-centre data, small sample size

- Very heterogeneous patient population.
- Variety of trial designs:
  - Dose-escalation vs known dose level
  - All solid tumours vs restricted cancer types
  - Monotherapy vs combination therapy
  - First-in-class vs me-too drug

⟹ Individualised approach is mandatory.

Thank you for your attention.

Questions ?