Impact of CTD and CTR on academic „Treatment Optimization Studies“ (TOS) and Treatment Registries (TR) in Pediatric Oncology

3 messages from a clinician

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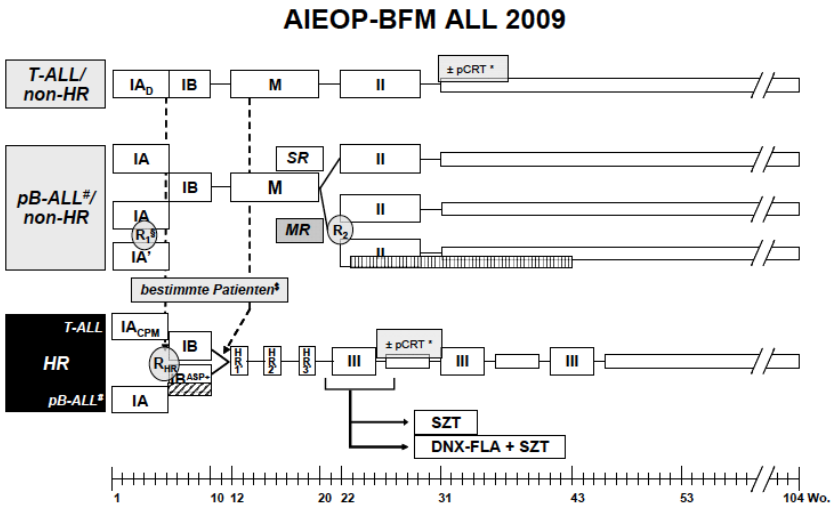
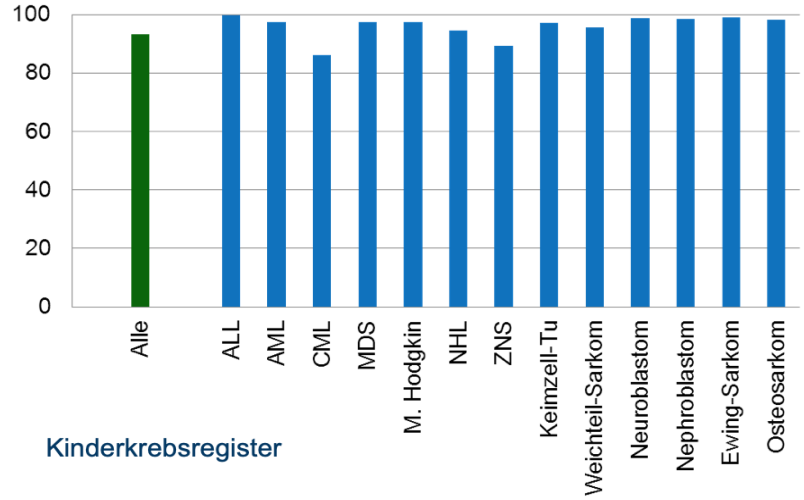
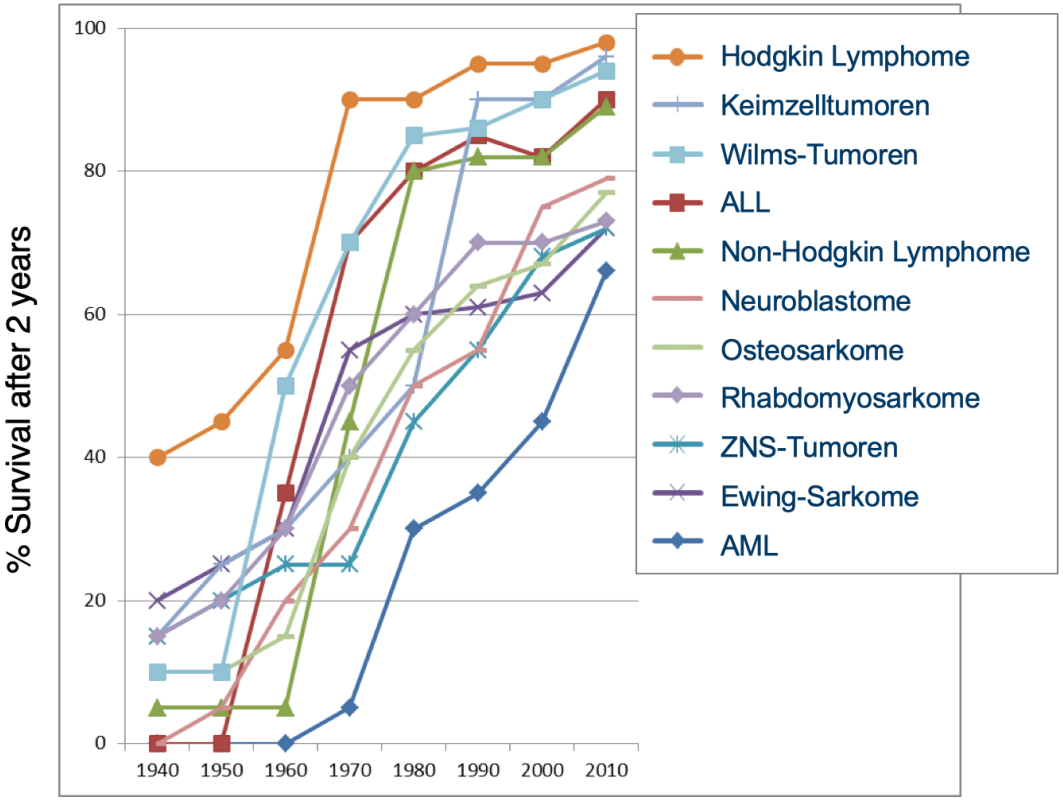
Message 1: Impact of TOS on cancer survival in Ped Onc







Rossig C et al. Pediatr Blood Cancer. 2013 Oct;60(10):1574-81

Message 2: Under CTD Academic TOS disappeared and Tumor Registries increased

Observations:

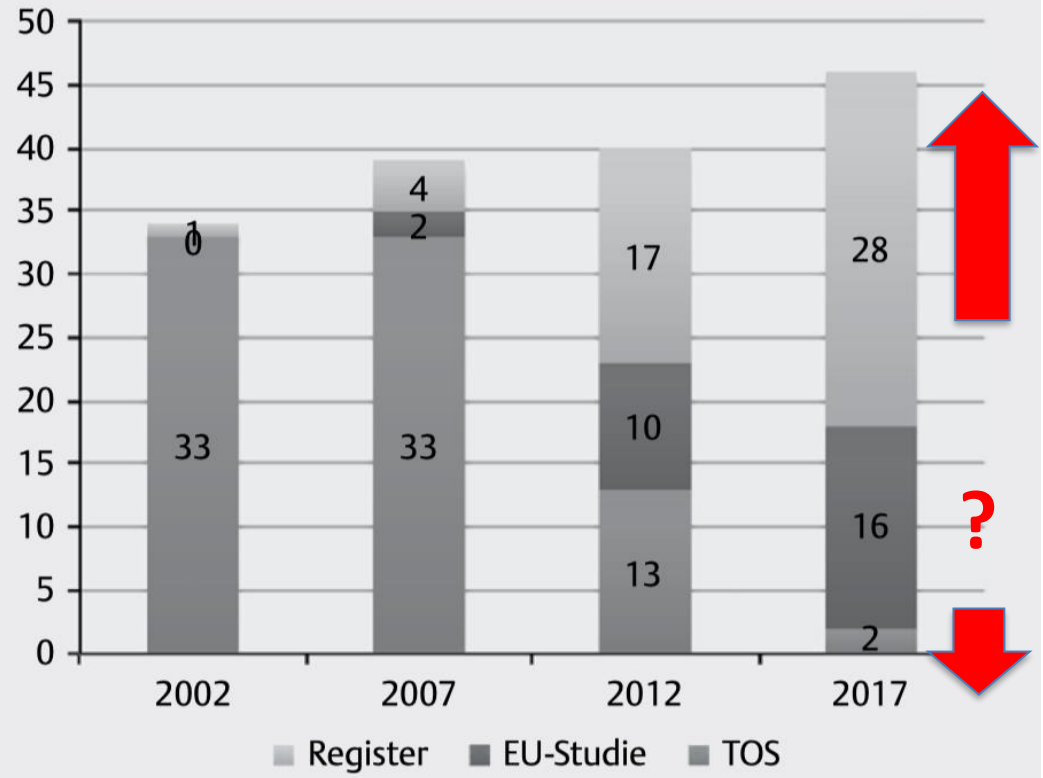
- Costs 10-fold
- Time 10-fold

Ped Academia cannot further finance TOS

? Pharma trials are no adequate substitute as

- Ped cancers are rare (return of investment) and
- actionable mutations are infrequent

Registries appear as remaining instrument for quality assurance and clinicians guidance

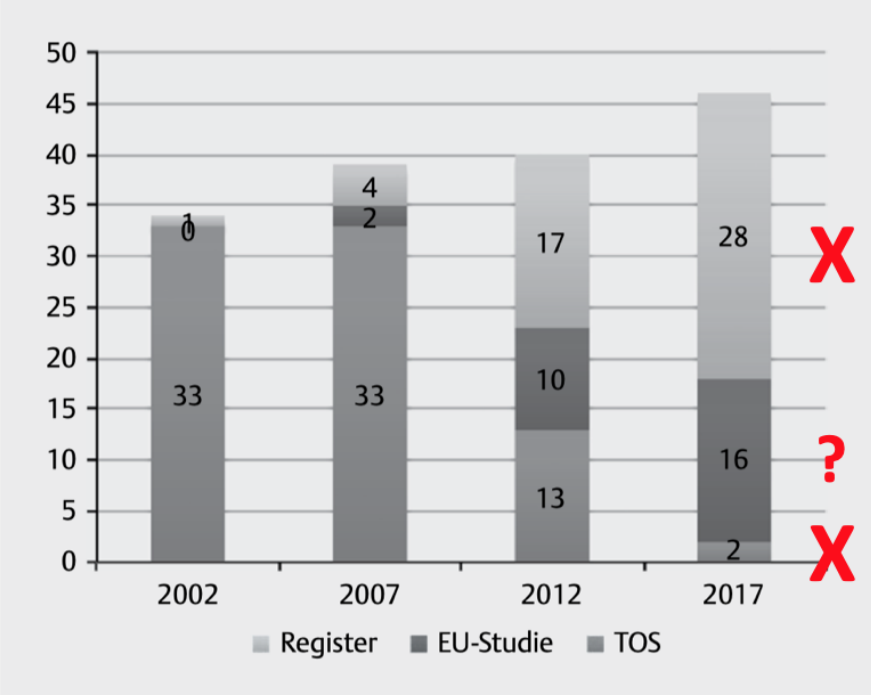


►**Abb. 1** Änderungen in der Zahl der Studientypen über die Zeit. Abfrage der GPOH Studiengruppenleitungen zur Zahl der klinischen Registern, Therapieoptimierungsstudien (TOS) und Arzneimittelstudien nach EU-Richtlinie (EU Studie) für die Jahre 2002, 2007, 2012 und 2017.

Klingebiel T Klin. Päd. 2020

Message 3: Impact of CTR and guidelines on Ped Onc Reg

- What is "**normal clinical practice**"? (CTR, Definitions, Article 2)
- FDA, U.S.A. (6/2000) .... Phase 3 pediatric oncology studies are generally the postapproval **standard of care** for children
- **Within the last months NCA interpretation of CTR in Germany lead to disappearance of many Ped Tumor Registries!**



??:

What has it to do with Ethics? Oncol. patient´s safety is in jeopardy without the instruments of TOS and disease-oriented registries (patient centricity and innovation)

What has it to do with guideline development and methodology? Please refrain from creating guidelines carrying narrow interpretations of the CTR. E.g. leave the definition of „normal clinical practice" to Medical Societies