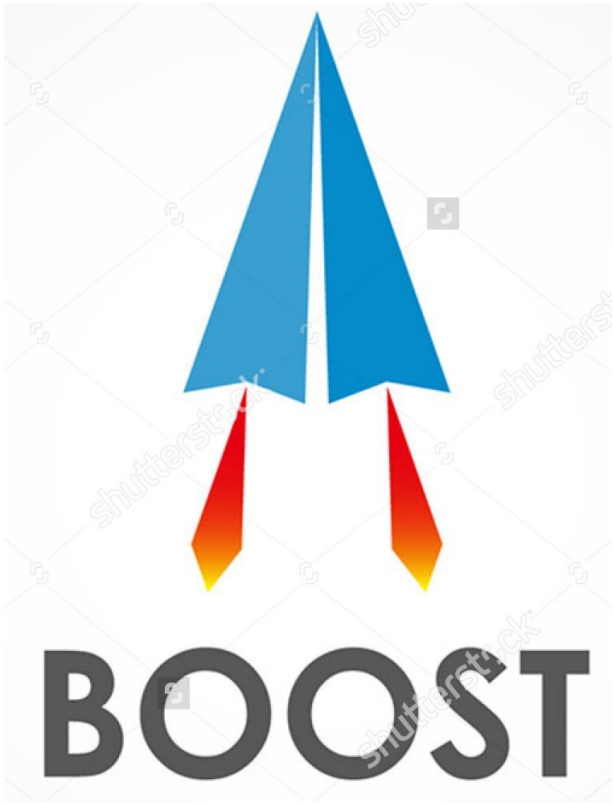
Leids Universitair Medisch Centrum

Boost vs no-boost voor orgaanpreservatie in laag-mid rectumcarcinomen

FP Peters, radiotherapeut-oncoloog

LUMC

LEIDEN



Achtergronden

- Assisi Think Tank Meeting (ATTM) 3-2017
- ‘T2 casus’
- Focus orgaanpreservatie

Achtergronden

- Lopende studies:
  - oncologische uitkomsten
  - evaluatie strategie
- Toekomst:
  - optimaliseren technieken mbt
    - pCR-rate
    - toxiciteit
- TESAR/STAR-TReC:
  - kleinere doelgebieden
  - lagere dosis RTx/CTx

Doel

Hogere orgaanpreservatie-rate met lagere toxiciteit en goede functionele uitkomsten in laag-mid rectumcarcinomen door kleinere velden en hogere tumordosis.

Eindpunten

Primair (composite):

- Stoma rate na 2* jr
- Functionele uitkomsten/QOL

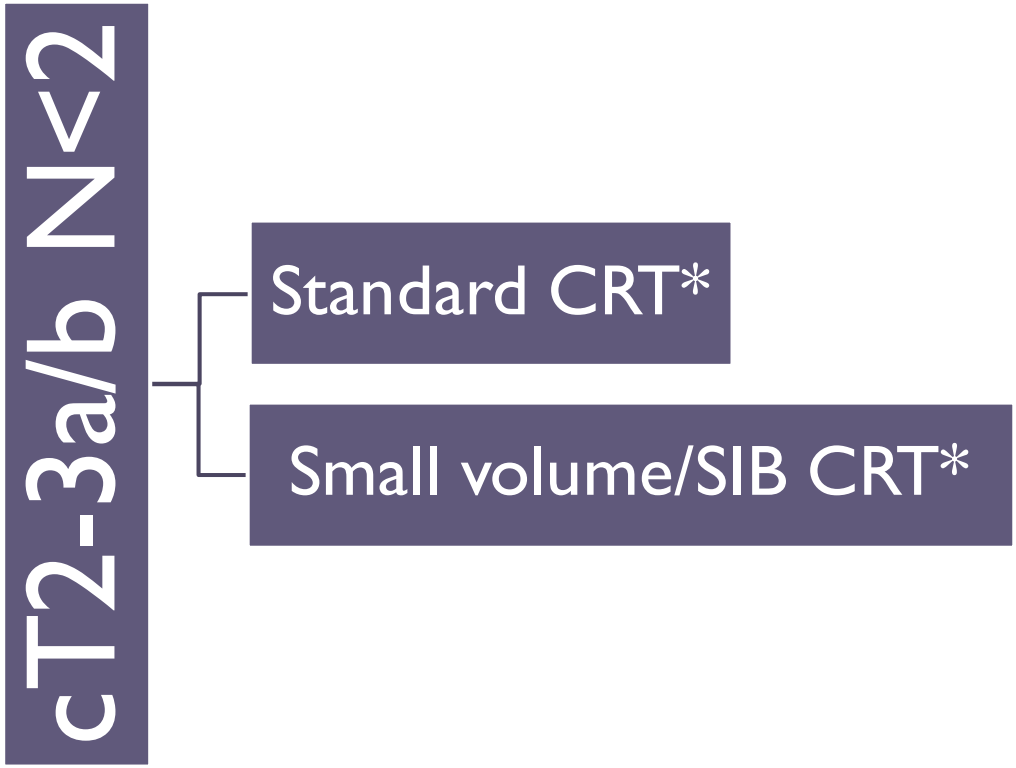
Secundair:

- Toxiciteit CRT
- ‘Organ preservation rate’
- Post-operative complicaties
- ‘Pelvic failure rate’
- 2jr DFS
- OS

Patienten

- cT2-3a/b
- N<2 peritumoral
- No extramesorectal LN
- EMVI-
- Rectal tumor with the lower border max 5 cm from anorectal junction on sagittal MRI
- Tumor size < 4 cm
- <50% circumference

Design



*Na CRT standaard organ preservation strategie:

- completion TME for non/poor-responders
- watch&wait strategy good responders (within current international databases)
- Local excision in case of persisting or growing small residu

Experimentele arm

25x1,8 Gy + SIB 25x 2,35 Gy

(EQD2(3)=43,2 Gy, EQD2(10)=44,3 Gy)

(EQD2(3)=62,9 Gy, EQD2(10)=60,5 Gy)

OR

28x1,65 Gy + SIB 28x2,25 Gy

(EQD2(3)=43 Gy, EQD2(10)= 44,9 Gy)

(EQD2(3)=66,15 Gy, EQD2(10)= 64,3Gy)

- capecitabine on radiation days
- mesorectal radiotherapy with SIB on tumor and nodes>1 cm

Te bepalen

- Boost technieken
- Overlap STAR-TReC
- NL patiënten geen standaard arm
- Primair eindpunt mbt functionele uitkomsten, LARS?

- Cohort multiple randomised control (cmCRT) trial design?

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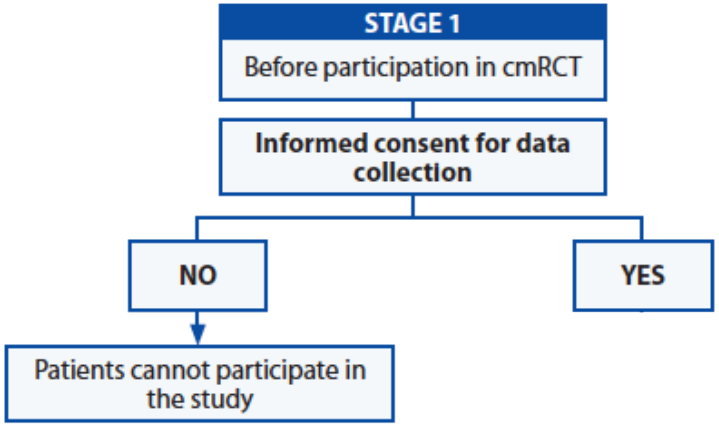
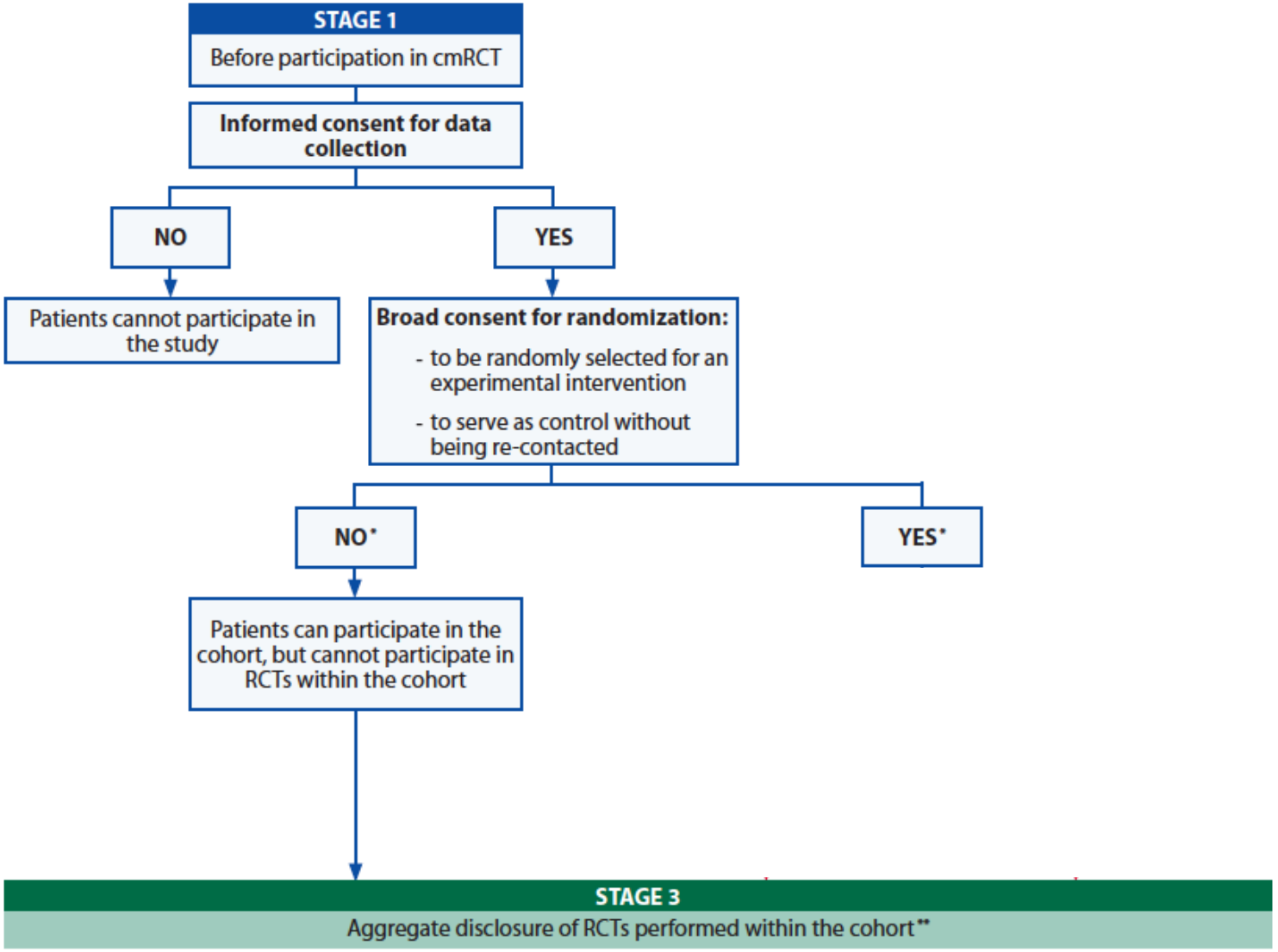
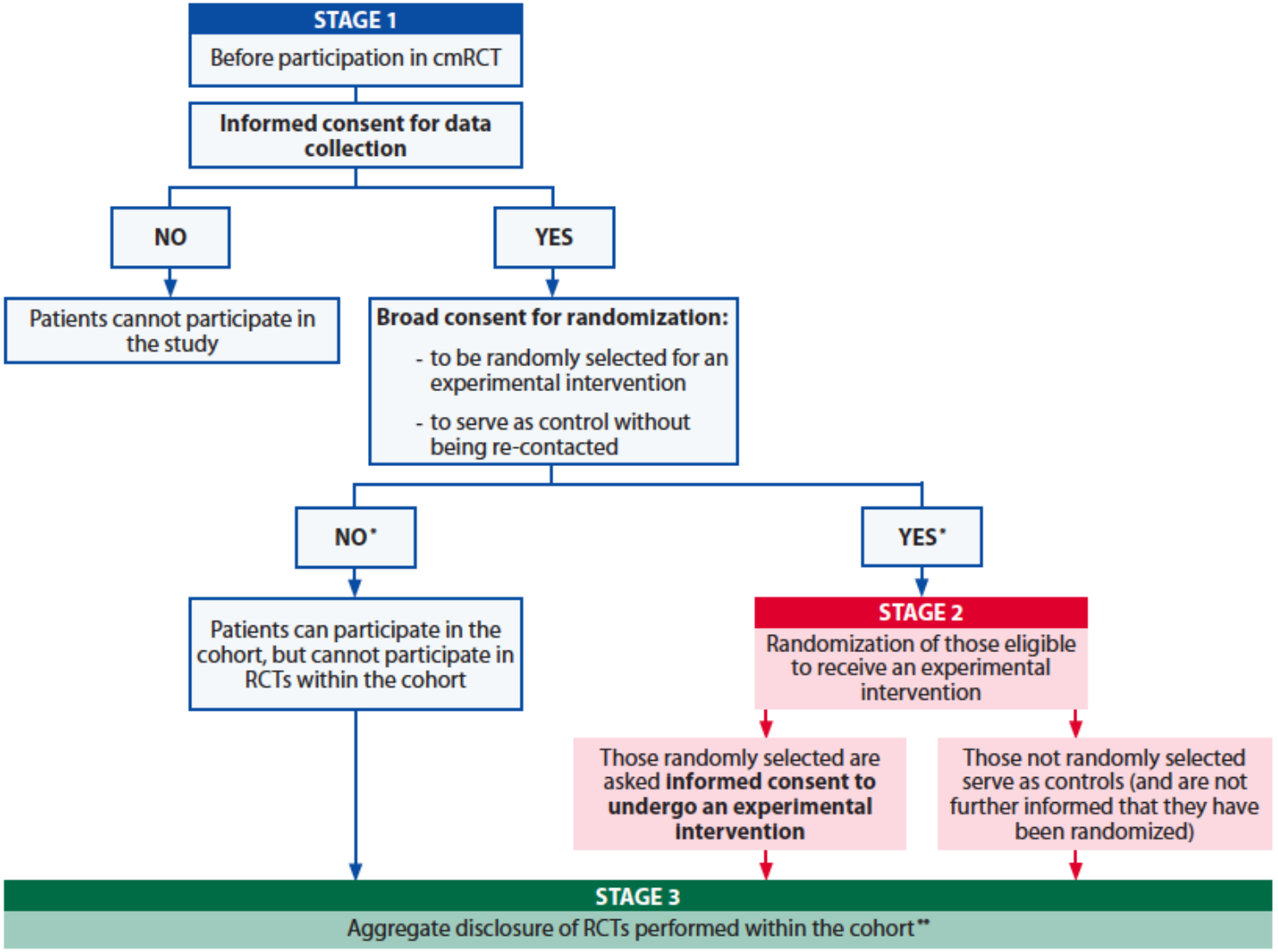
Stage informed consent model for cmRCT

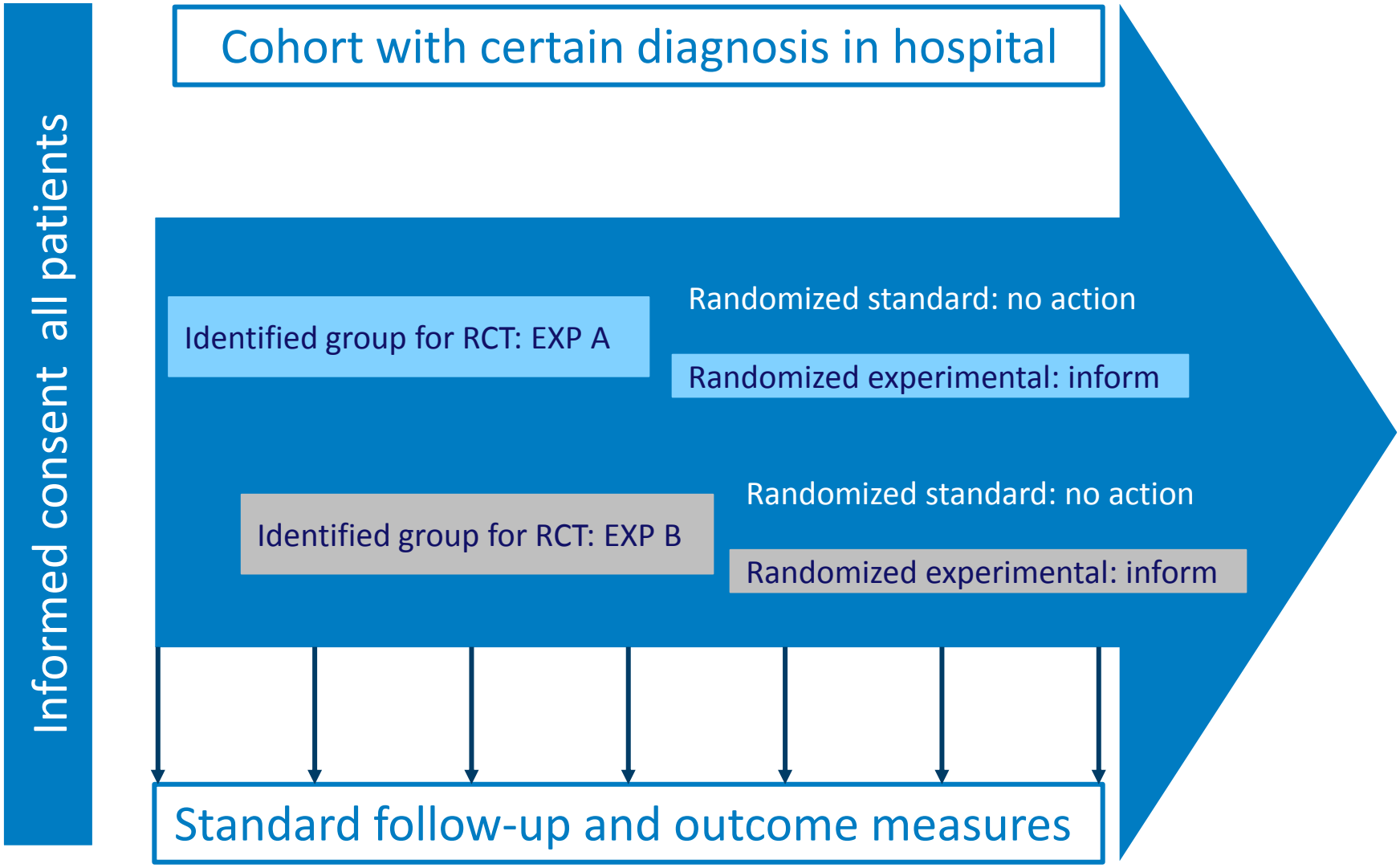


Stage informed consent model for cmRCT



Stage informed consent model for cmRCT




Informed consent all patients
Cohort with certain diagnosis in hospital
Identified group for RCT: EXP A
Randomized standard: no action
Randomized experimental: inform
Identified group for RCT: EXP B
Randomized standard: no action
Randomized experimental: inform
Standard follow-up and outcome measures

Advantages cmRTC

Facility for multiple Randomized Comparisons

- Increased efficiency
- Increased comparability between trials
- Flexibility to deal with changes in standard therapy

Patient centered informed consent

- More representative patients

Challenges

- Statistics (adaptive design)
- Ethics