

# PORTEC-4a kick-off

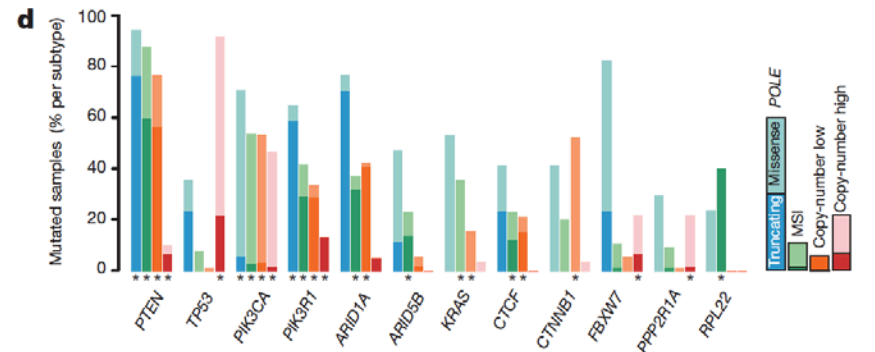
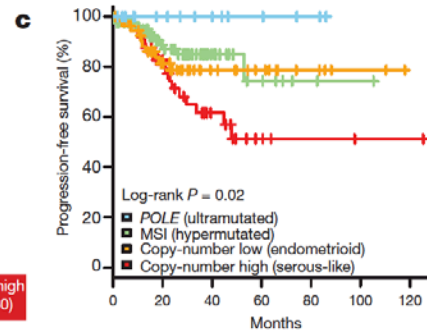
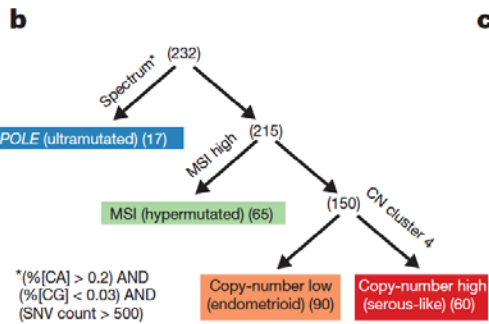
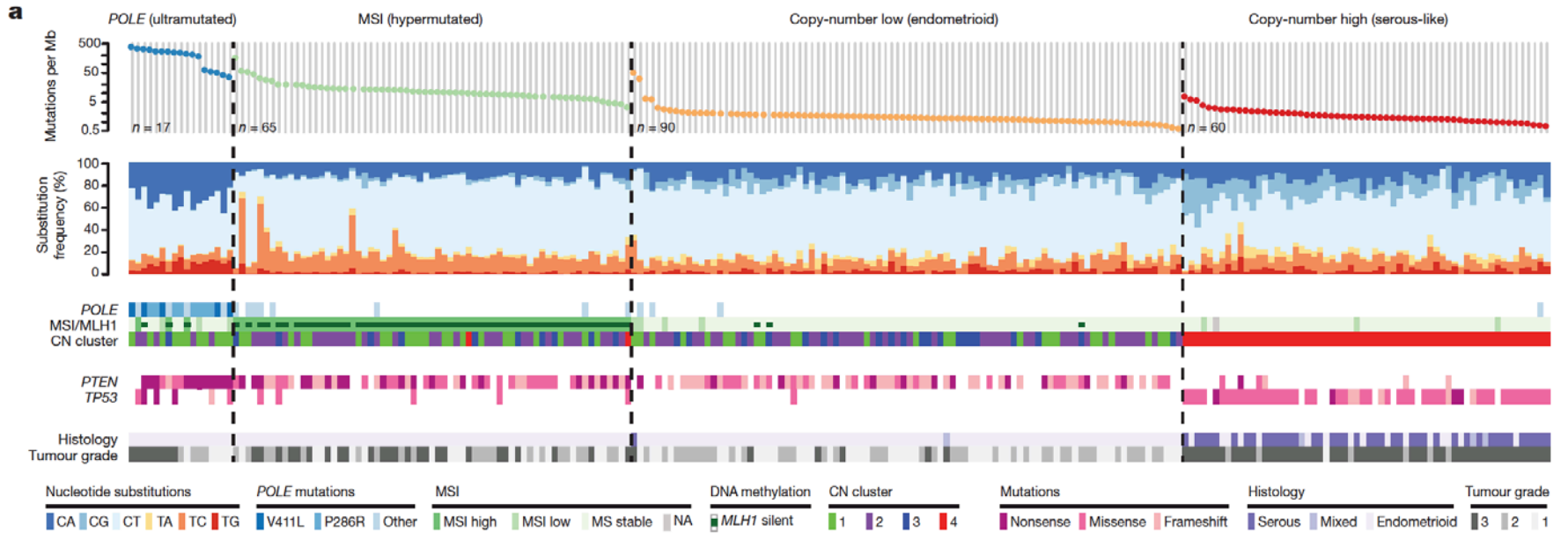
Utrecht, June 2, 2016



Carien Creutzberg

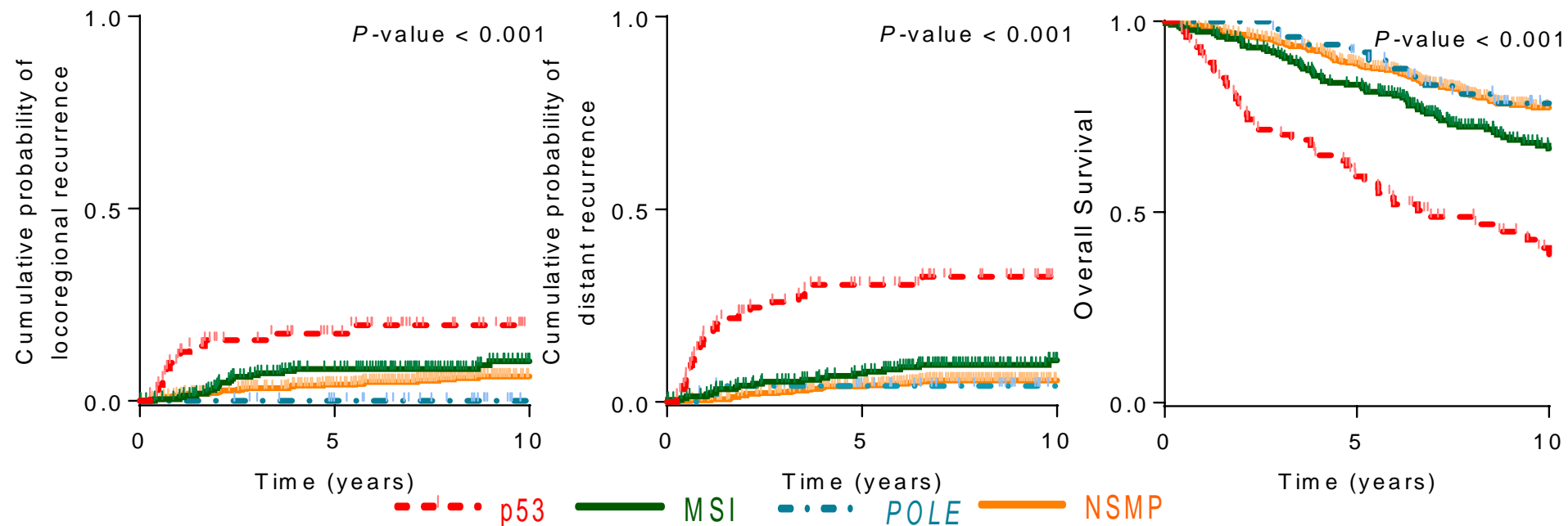
Leiden University Medical Centre, The Netherlands

# Molecular characteristics of endometrial cancer

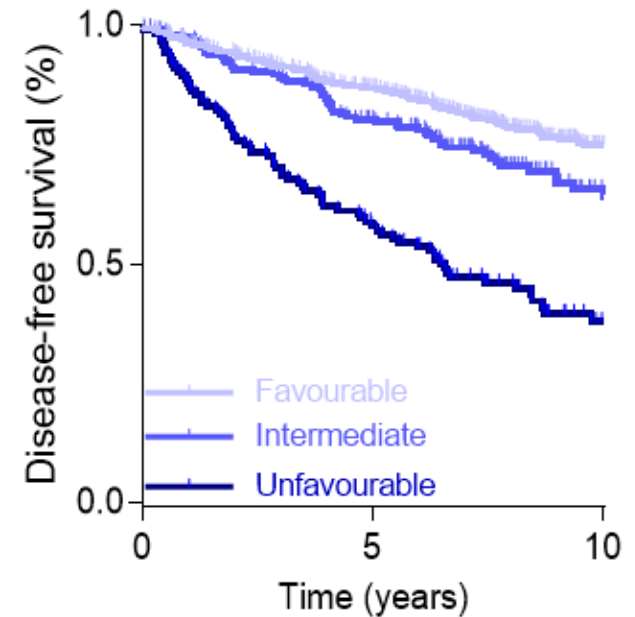
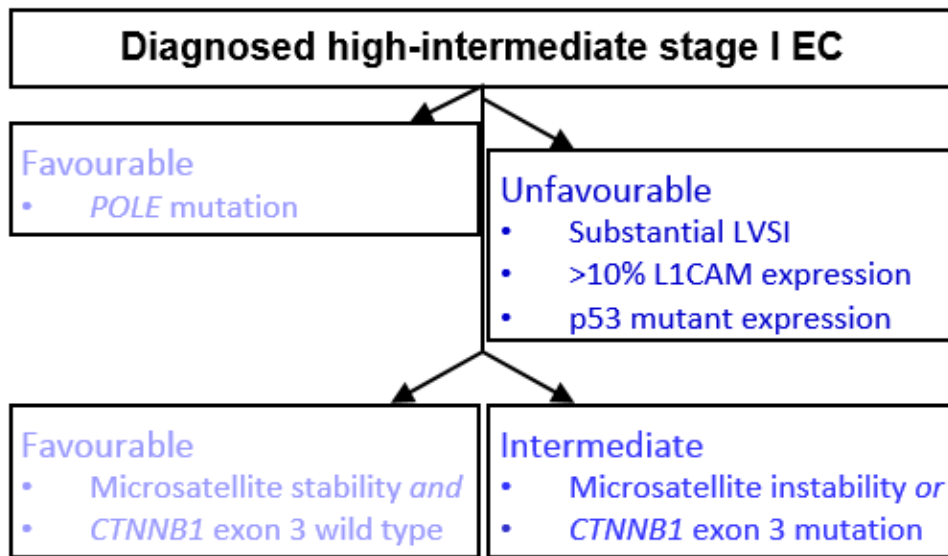


# Molecular analysis PORTEC-1 and 2 cohort (N=834)

## The 4 TCGA subgroups by surrogate markers in PORTEC-1/2

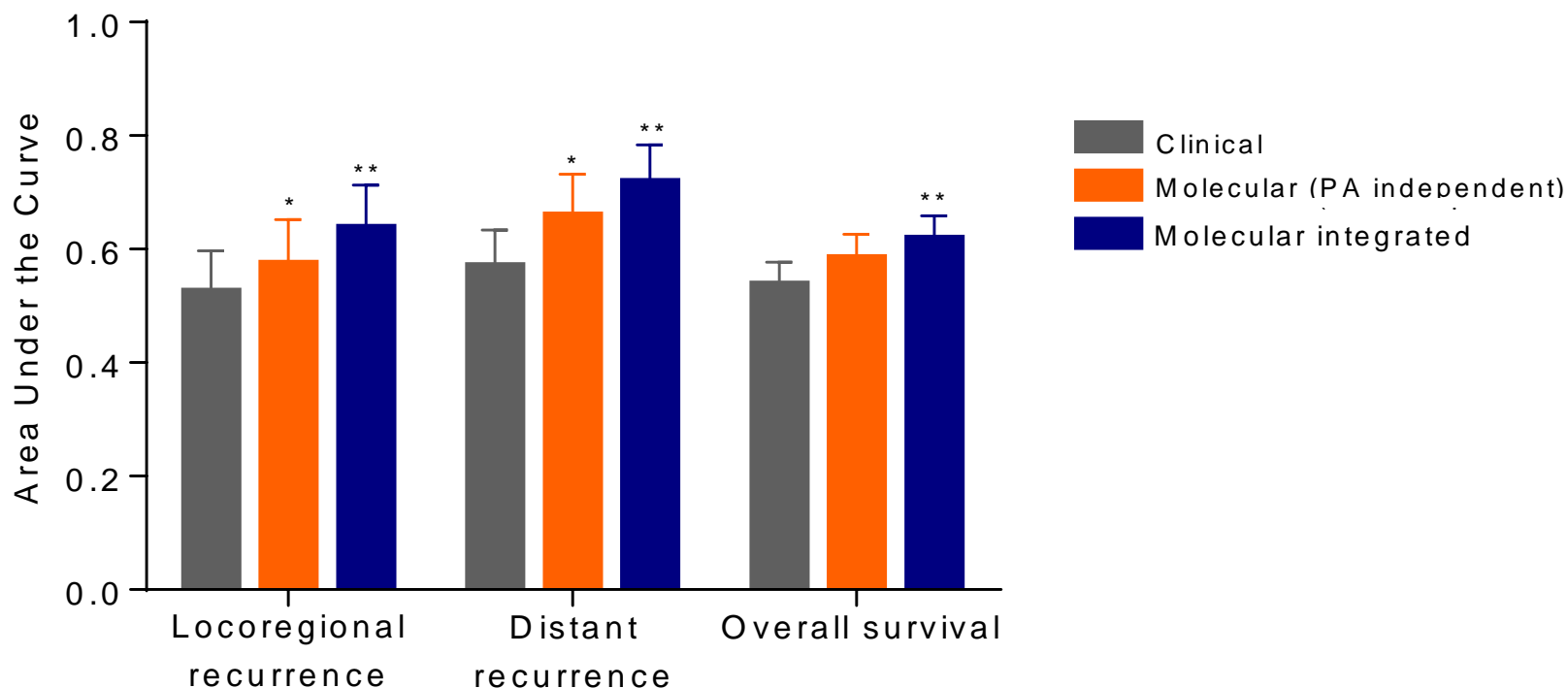


# Molecular integrated risk profile PORTEC-1/2 cohort



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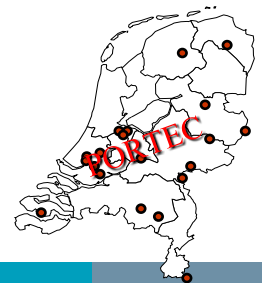
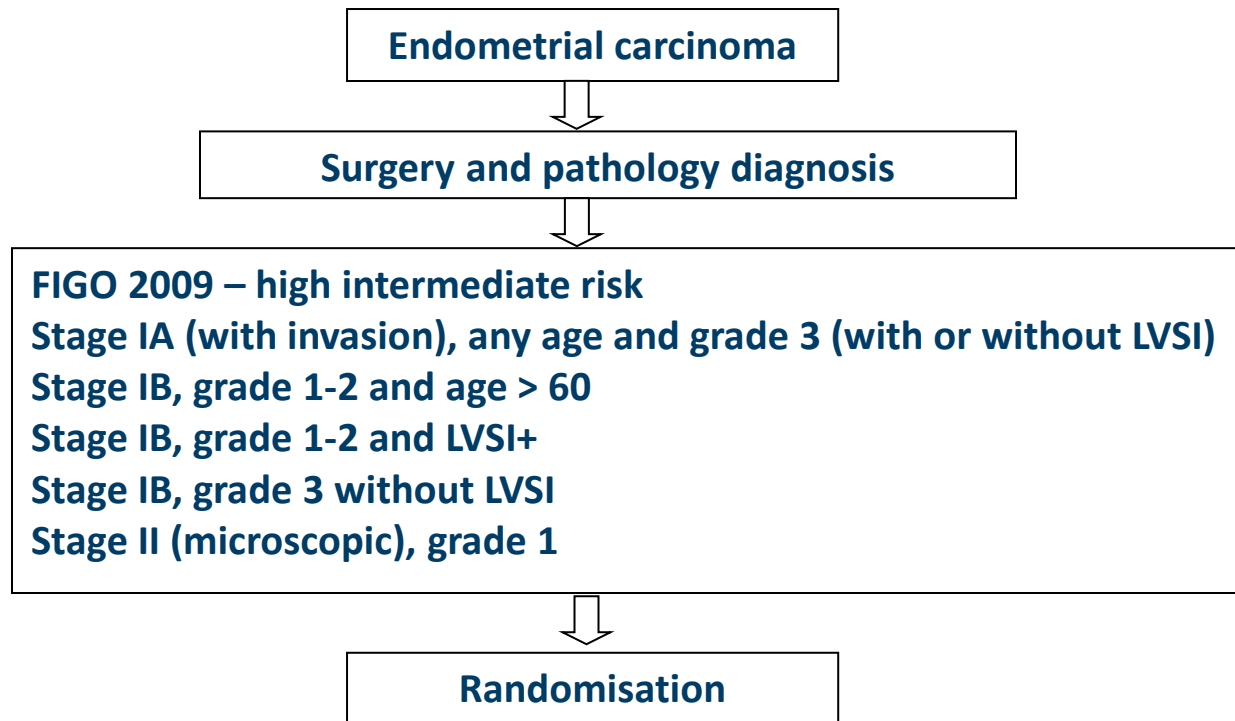
N=834



- Molecular integrated risk profile is a stronger risk stratification model with improved risk prediction
- Decrease overtreatment and undertreatment

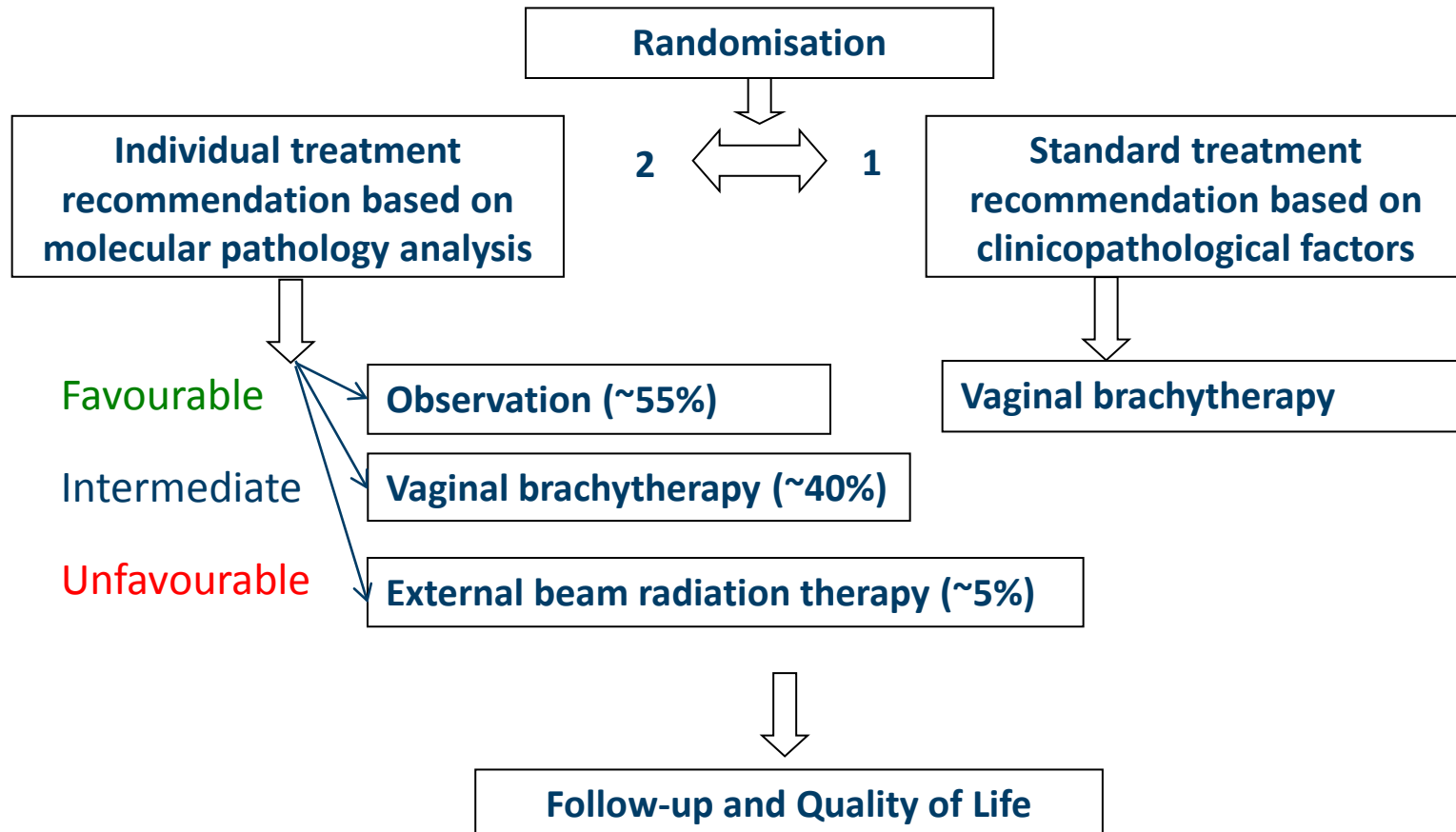
# New PORTEC-4a trial design

- **Molecular integrated vs standard indications for adjuvant treatment:**



# New PORTEC-4a trial design

- Molecular integrated vs standard indications for adjuvant treatment:



## PORTEC-4a – logistiek en kick-off

- Alle documenten op [www.msbi.nl/portec4](http://www.msbi.nl/portec4)
- Investigator Site File op orde maken - en onderhouden
- Lokale afspraken met IKNL datamanagers, research vpk
- Informeer svp de gynaecologen en pathologen in je regio
- Randomisatie site werkt per 3-6-2016 (via IKNL tenzij anders afgesproken, en met rando form gefaxt)
- Denk aan de subject screening log!
- Monitoring plan volgt
- NTR wordt aangepast
- QA van 1e of 2e patient in studie



## PORTEC-4a – logistiek bij nieuwe pat

- Informatie gesprek met patient, PIF (2-voud) en QOL met adres formulier en antwoordenvelophe mee
- Telefonische of poli afspraak maken voor (aanvullende) vragen en informed consent (incl consent voor gebruik restweefsel!)
- IC tekenen met die datum, en QOL en adresform invullen.
- Randomisatie form invullen en naar IKNL of locale contact persoon -> randomisatie, materiaal wordt door PA opgevraagd
- Afh van arm: afspraak voor brachytherapie maken, of voor bespreking profiel (2 weken)
- Bij brachy of uitslag-consult: 1 ex getekende PIF/IC voor file, 1 voor patient, QOL en adresform voorzien van studienummer en in antwoordenvelophe insturen
- **Subject screening log invullen**

## PORTEC-4a - started June 1<sup>st</sup> 2016

- Pilot phase: N = 50 (Netherlands)
  - *Endpoints: logistics, patient acceptance*
- Proceed into full trial (international)
  - *Endpoints: vaginal recurrence, recurrence-free survival, AE and QOL, health costs*
- Validation of molecular profile procedure in pathology centers - > 3-4 in NL and in participating countries
- NCRI UK and ANZGOG planning to participate

