23RD INTERNATIONAL EXPERTS SYMPOSIUM

CRITICAL ISSUES in aortic endografting 2019

LIVERPOOL UNITED KINGDOM MAY 23-24

Personalised Decision Making
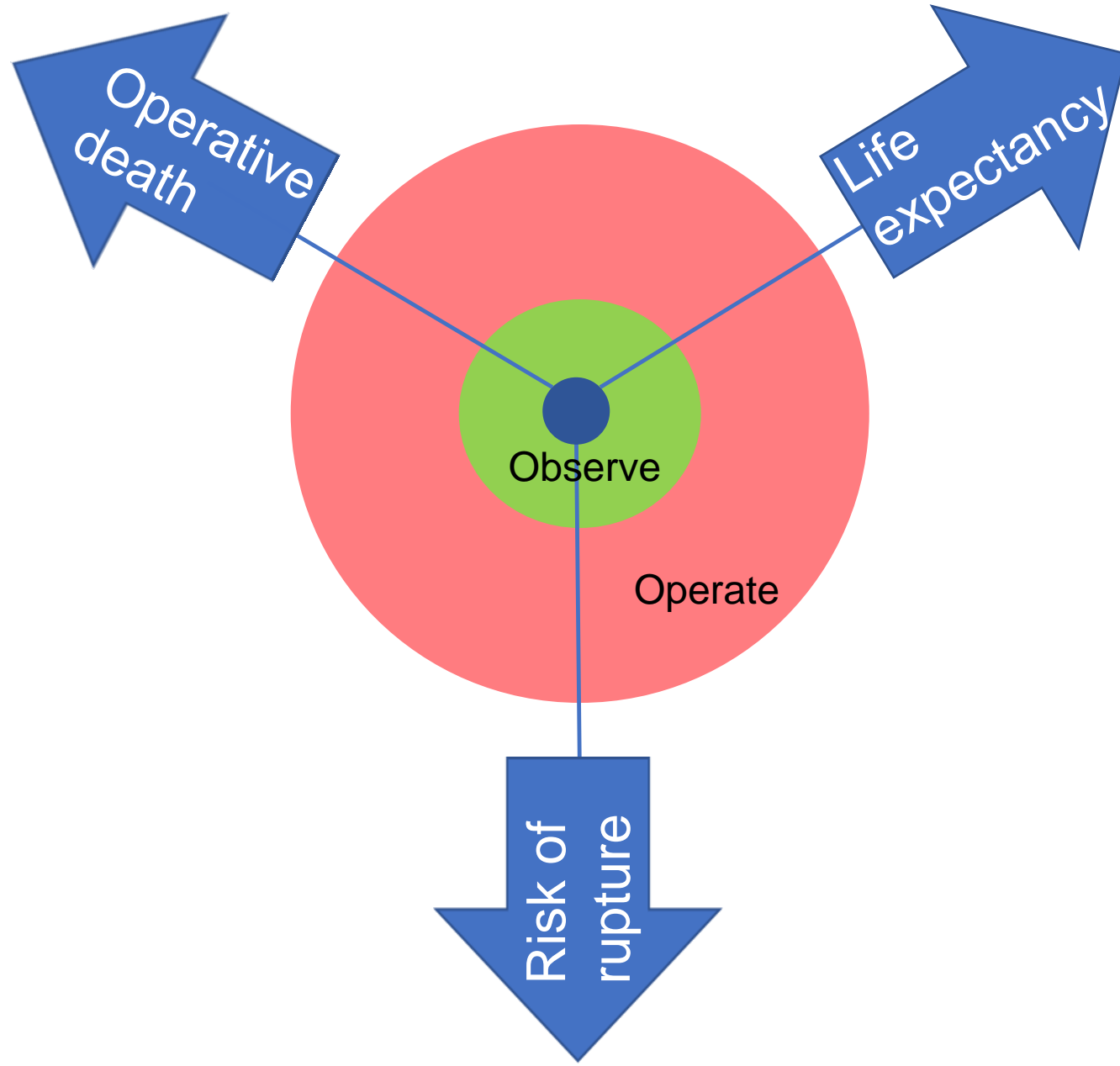## S.R.Vallabhaneni

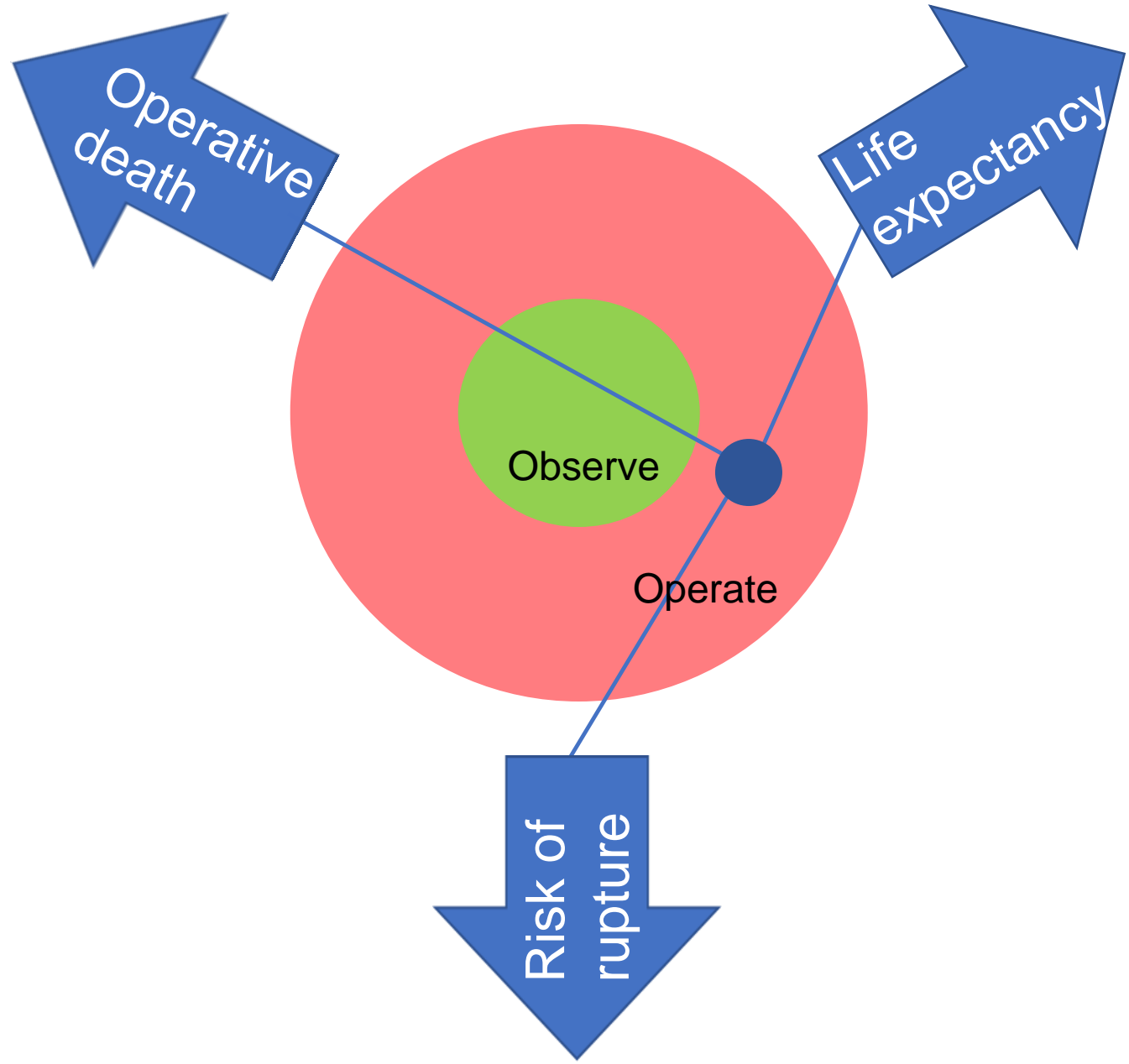**www.critical-issues-congress.com**

Disclosure

Speaker name: S.R.Vallabhaneni.

I have the following potential conflicts of interest to report:

Unrestricted research grant: Cook medical

Operative death

Life expectancy

Observe

Operate

Risk of rupture
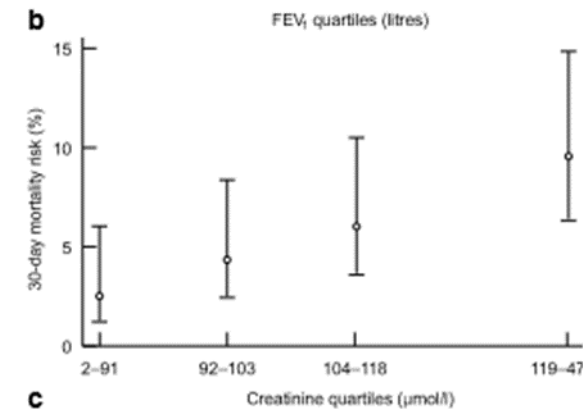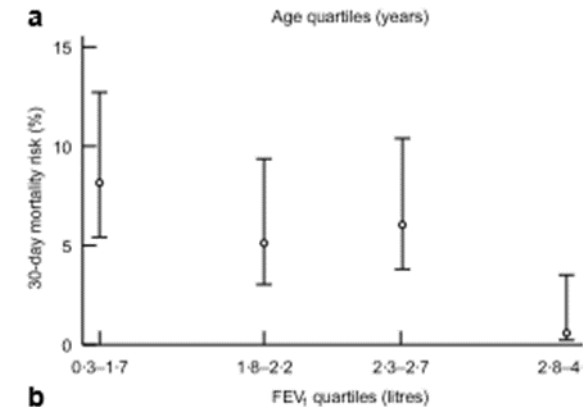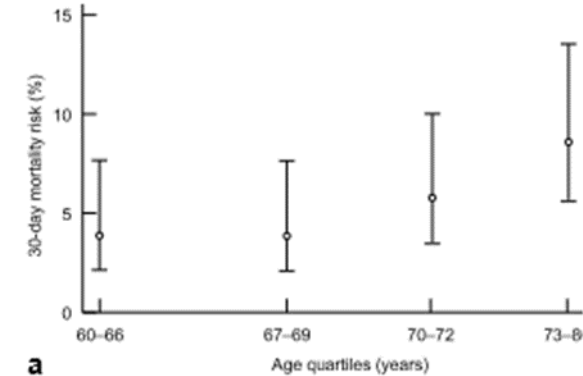
Limitations

- Utility/Risk parameters are continuous

- These parameters / proxies are treated binary / inconsistent

- Inconsistent application of information

- Lack of tools

- Lack of personalization

- Another short coming of NICE committee

What has been done so far ?

- Rescan group ('98-'05)
- VGNW ('99-'09)

TABLE 21 Discrete event simulation model outputs for vignette A with initial AAA diameter of 4.0 cm
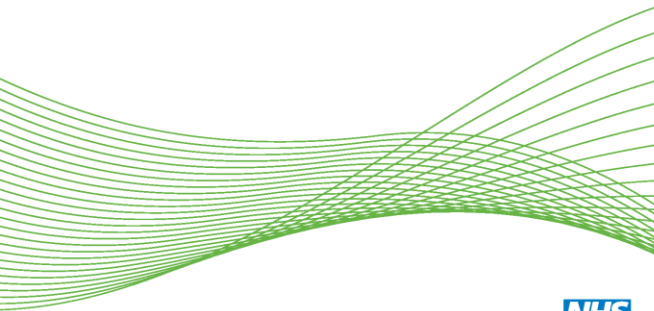
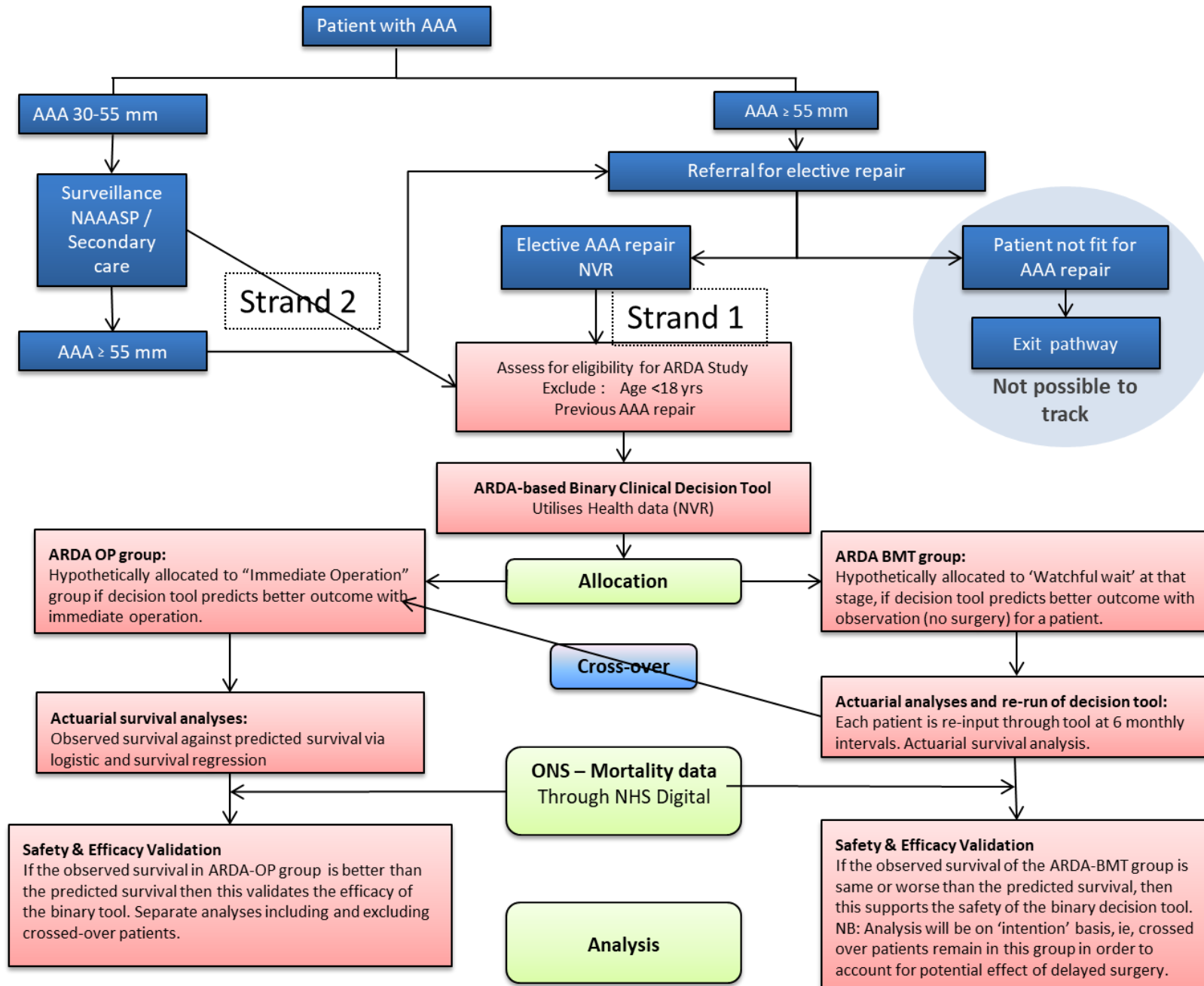| Output	Repair at						No elective repair
	4.0 cm	4.5 cm	5.0 cm	5.5 cm	6.0 cm	6.5 cm	
Median life expectancy (years)	76.92	76.95	76.87	76.83	76.81	76.68	75.50
1-year survival	0.97	0.97	0.97	0.97	0.97	0.97	0.97
2-year survival	0.94	0.94	0.94	0.94	0.94	0.94	0.94
5-year survival	0.83	0.83	0.82	0.83	0.83	0.83	0.83
10-year survival	0.60	0.60	0.60	0.60	0.59	0.58	0.51
Other cause of death (prior to repair)	0.00	0.08	0.13	0.19	0.24	0.29	0.53
Death due to rupture	0.00	0.00	0.00	0.01	0.01	0.02	0.38
Rupture survival	0.00	0.00	0.00	0.00	0.00	0.01	0.10
Postoperative survival	0.99	0.91	0.86	0.79	0.73	0.67	NA
Growth rate at size	0.24	0.30	0.36	0.42	0.48	0.48	NA
1-year rupture probability at intervention	0.00	0.00	0.00	0.00	0.01	0.02	NA
Probability of repair	1.00	0.92	0.87	0.81	0.75	0.69	NA
In-hospital mortality on repair	0.01	0.01	0.01	0.02	0.02	0.03	NA
5-year postoperative survival	0.84	0.79	0.76	0.72	0.69	0.65	NA
10-year postoperative survival	0.61	0.51	0.45	0.40	0.34	0.30	NA
Median age at repair (years)	65.00	68.00	69.00	70.50	71.75	73.00	NA
Median years to reach size	0.00	3.00	4.00	5.50	6.75	8.00	NA

? Ready for prime time

- DES 'engine' too slow

- Contextualisation of output

- Not validated

- Dynamisation

Personalised Aneurysm Management (PAM)

- *DES 'engine' too slow*

- *Contextualisation of output*

- *Not validated*

- *Dynamisation*

- New coding and validation

- UK and Europe wide survey completed

- Binary decision tool developed

- Validation started

PAM

Patient with AAA

AAA 30-55 mm

AAA ≥ 55 mm

Referral for elective repair

Surveillance NAAASP / Secondary care

Strand 2

Elective AAA repair NVR

Strand 1

Patient not fit for AAA repair

Exit pathway

Not possible to track

AAA ≥ 55 mm

Assess for eligibility for ARDA Study
Exclude : Age <18 yrs
Previous AAA repair

ARDA-based Binary Clinical Decision Tool
Utilises Health data (NVR)

ARDA OP group:
Hypothetically allocated to "Immediate Operation" group if decision tool predicts better outcome with immediate operation.

Allocation

ARDA BMT group:
Hypothetically allocated to 'Watchful wait' at that stage, if decision tool predicts better outcome with observation (no surgery) for a patient.

Cross-over

Actuarial survival analyses:
Observed survival against predicted survival via logistic and survival regression

Actuarial analyses and re-run of decision tool:
Each patient is re-input through tool at 6 monthly intervals. Actuarial survival analysis.

ONS – Mortality data
Through NHS Digital

Safety & Efficacy Validation
If the observed survival in ARDA-OP group is better than the predicted survival then this validates the efficacy of the binary tool. Separate analyses including and excluding crossed-over patients.

Safety & Efficacy Validation
If the observed survival of the ARDA-BMT group is same or worse than the predicted survival, then this supports the safety of the binary decision tool. NB: Analysis will be on 'intention' basis, ie, crossed over patients remain in this group in order to account for potential effect of delayed surgery.

Analysis

Validation of a binary decision tool

- Regulatory approvals

- Data sharing

- Data analysis

- Expected to be completed by Oct 2019

Personalised Aneurysm Management
Research plans

- Dynamisation 'Ever-greening'

- Combined tool

- Prospective evaluation

- Complex study with multiple work-packages

- Opportunity for a true collaborative project

- Potential to help patients, physicians and policy makers

Thank you