

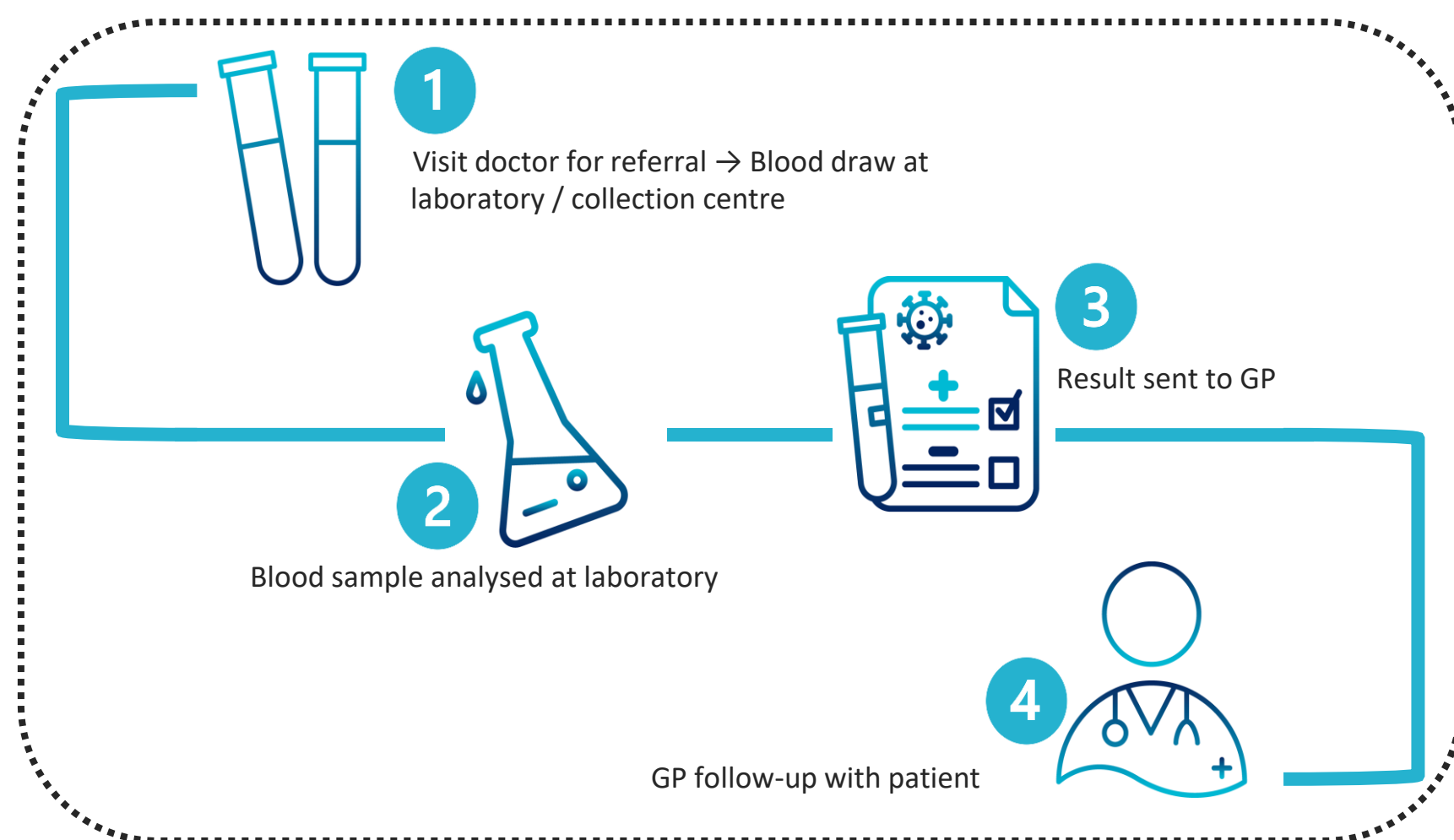
#3529: A prospective, cross-sectional, multi-centre study to evaluate the clinical performance of the ColoSTAT in vitro diagnostic for the detection of biomarkers associated with colorectal cancer

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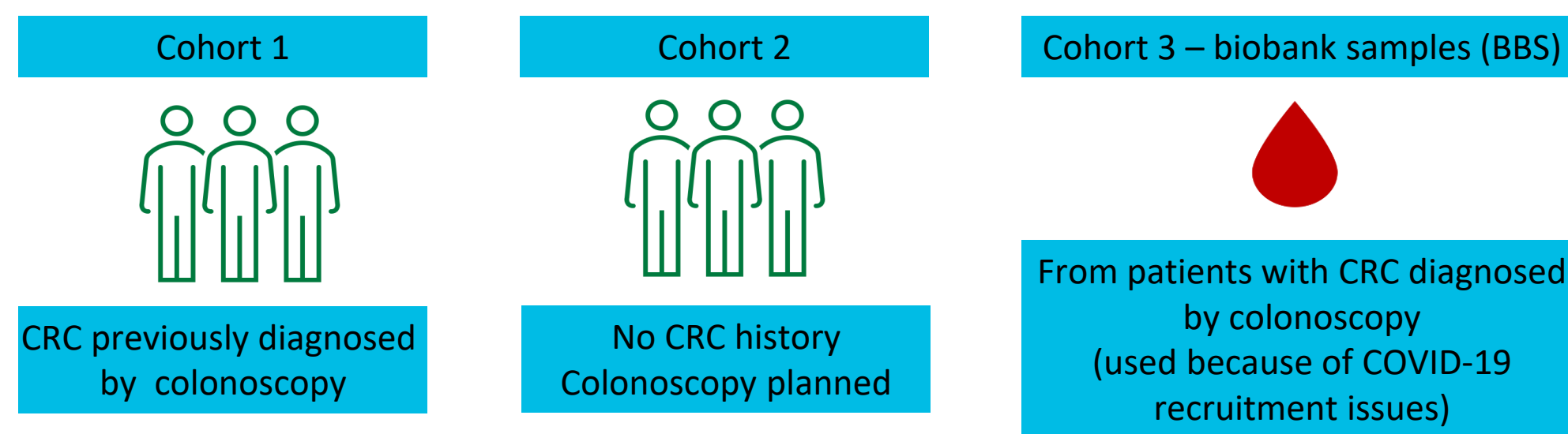
Background:

- Colorectal cancer (CRC) survival rates could be improved if more cancers were detected early.
- ColoSTAT is a simple blood test and algorithm that combines concentrations of 5 protein biomarkers with age and sex as an alternative to current CRC screening.



- In this study we compared the performance of ColoSTAT to colonoscopy in detecting CRC.

Methods:



- Primary endpoint:** ColoSTAT sensitivity $\geq 73\%$ (lower 95% confidence limit [LCL] $>60\%$), and specificity $\geq 90\%$ (LCL $>80\%$).
- Sensitivity by TNM stage was an exploratory endpoint (ACTRN12619000301167).

Comparing ColoSTAT to colonoscopy

estimated sensitivity **81.3%**
(95%CL 73.0%-87.4%)

estimated specificity **91.0%**
(95%CL 87.7%-93.5%)

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Results:

- Patient demographic characteristics were similar across cohorts; Cohort 1 (n=29), Cohort 2 (n=768) and BBS (n=192). The median age was 64 years (range 40 to 88) and 53.4% were female.
- Definitive ColoSTAT results were obtained for 22 patients in Cohort 1, 554 in Cohort 2 and 81 in BBS.

Table: Sensitivity & specificity of ColoSTAT vs colonoscopy

	All participants/BBS (n=989)
Definitive ColoSTAT result (indeterminant, invalid, no test)	657 (97, 208, 27)
Colonoscopy result available (no colonoscopy)	911 (78)
Definitive ColoSTAT and colonoscopy	603
ColoSTAT True +ve (A), False +ve (B), False -ve (C), True -ve (D)	91, 35*, 21, 354*
Sensitivity (95% CL) (A/[A+C])	81.3% (73.0%-87.4%)
Specificity (95% CL) (D/[B+D])	91.0% (87.7%-93.5%)
ColoSTAT sensitivity by TNM stage (95% CL) [#]	
I (A: n=14, C: n=2)	I: 87.5% (64.0%-96.5%)
II (A: n=21, C: n=2)	II: 91.3% (73.2%-97.6%)
III (A: n=12, C: n=1)	III: 92.3% (66.7%-98.6%)
IV (A: n=28, C: n=0)	IV: 100% (87.9%-100%)

BBS: biobank samples, CL: confidence limit, TNM: tumor, node, metastasis *Specificity calculated using the prospective cohorts [#]Exploratory endpoint; staging data available for BBS only

Conclusions:

- The primary endpoint was met.
- Sensitivity and specificity were comparable with published performance of faecal immunochemical test (FIT)¹.
- ColoSTAT may provide an alternative test for people who cannot, or will not take the FIT test.