

### RACE trial

A prospective Randomized multicenter study comparing horse Antithymocyte globuline (hATG) + Cyclosporine A (CsA) with or without Eltrombopag as front-line therapy for severe aplastic anaemia patients

A study by the Severe Aplastic Anaemia Working Party (SAAWP)  
Principal Investigators: Antonio Risitano and Régis Peffault de Latour  
Grant providers: Novartis and Pfizer

### Trial objective

The primary objective of this trial is to investigate whether Eltrombopag added to standard immunosuppressive treatment increases the rate of early (at three months) complete response in untreated aplastic anaemia patients.

The RACE trial is a prospective open label randomised phase III trial aiming to change standard practice in severe aplastic anaemia (SAA).

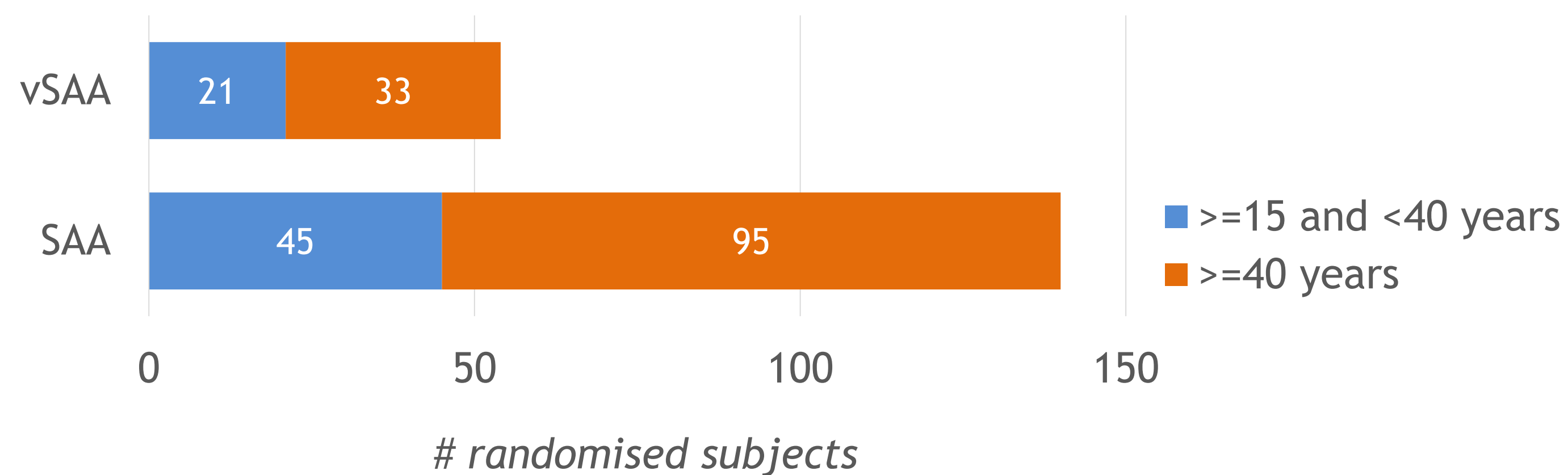
	Treatment	Dose (units)	Treatment Period
Arm A (standard):	ATGAM	40 mg/kg/day, iv	Day 1, 2, 3 and 4
	Cyclosporine A	5 mg/kg/day, po	Day 1-365
Arm B: arm A + Investigational drug	Eltrombopag	150 mg every 24 h, po	Day 14-90 (or 14-180)

Primary endpoint: rate of Complete Response (CR) at 3 months since start of treatment in naive SAA patients.

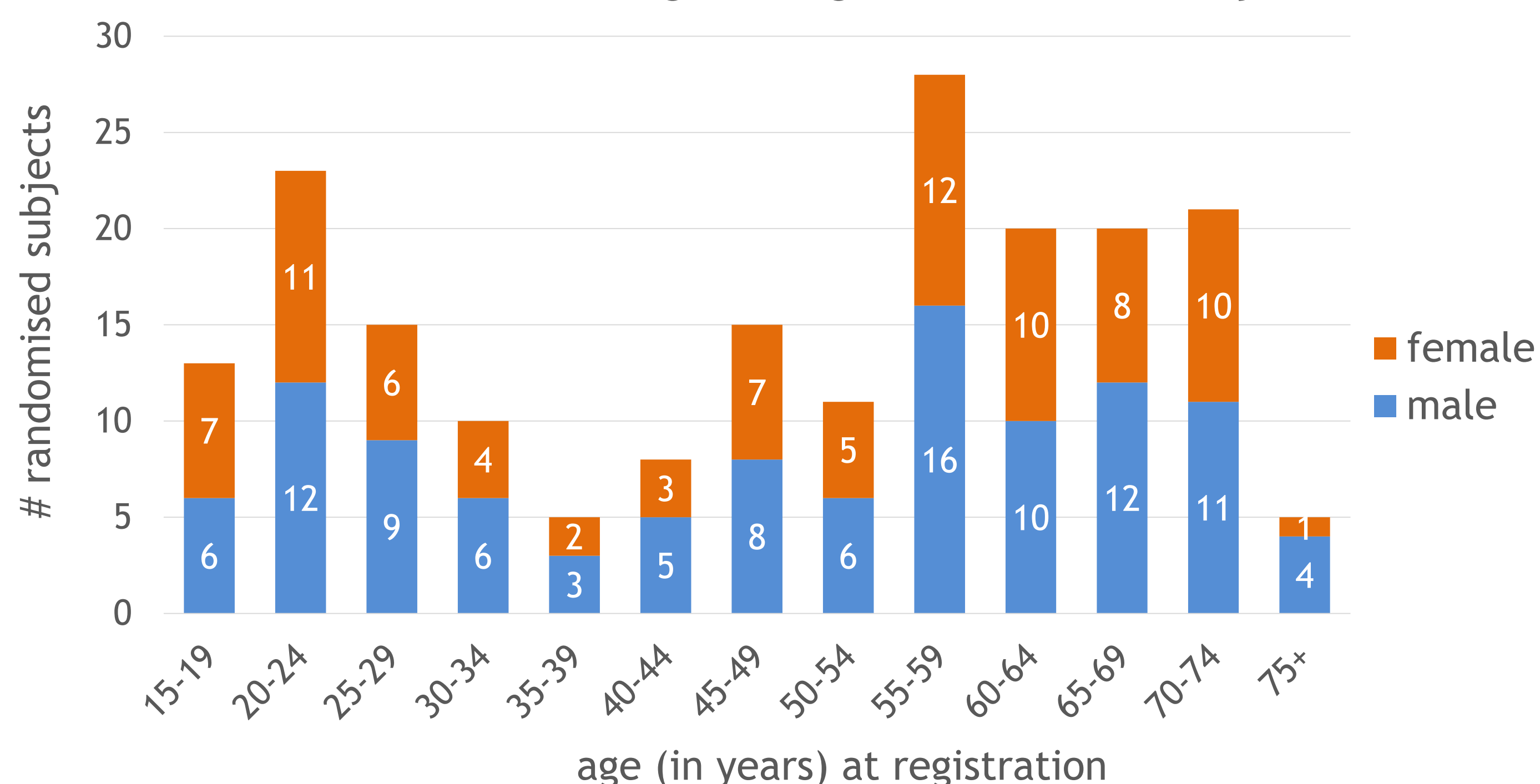
CR is defined as: haemoglobin >10 g/dL, absolute neutrophil count >1,000/μL and platelets >100,000 μL

### Baseline characteristics RACE subjects

Disease severity by age category



Distribution of age at registration RACE subjects



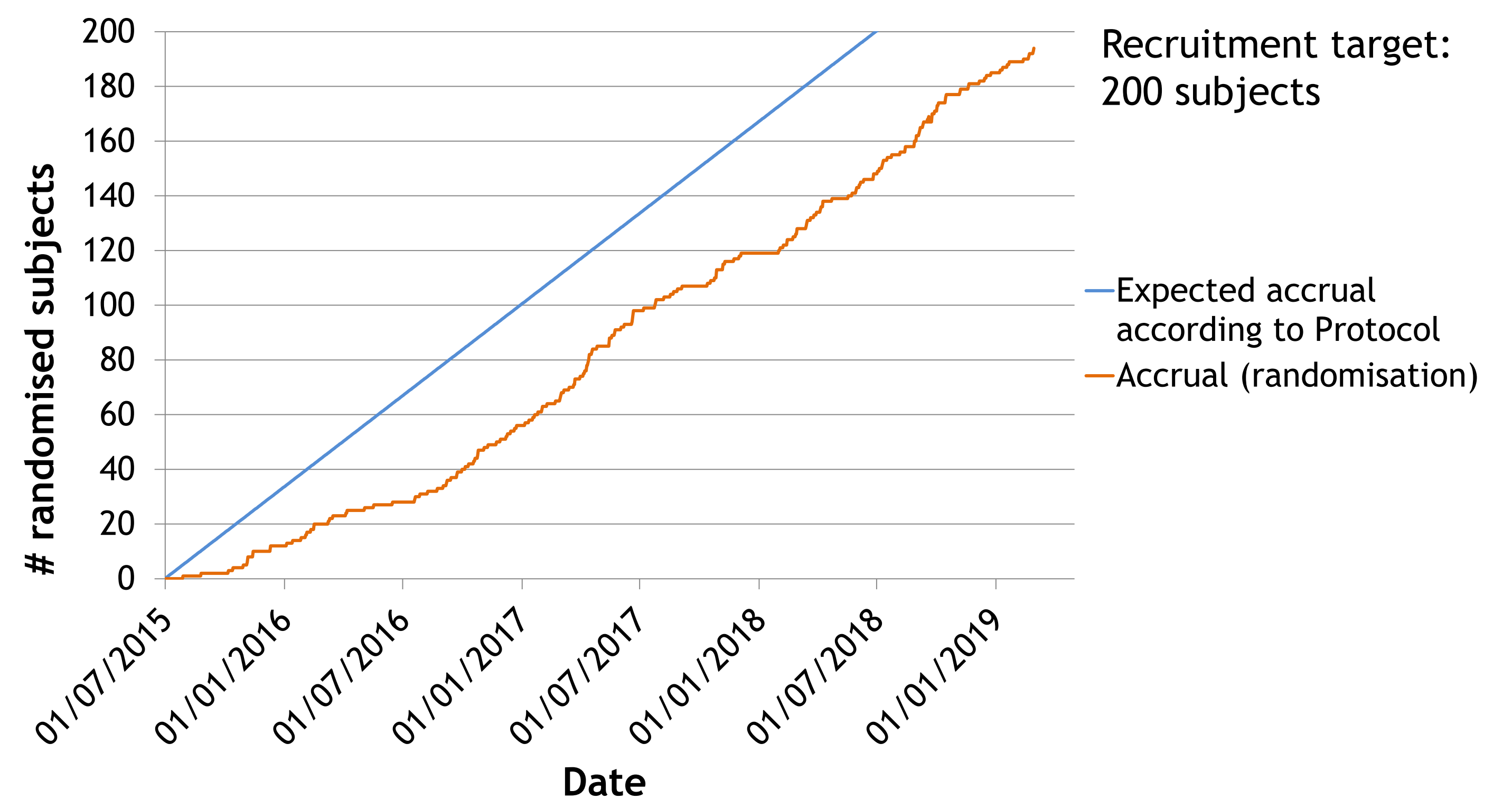
### Thank you!

Congratulations to all involved: the recruitment target of 200 subjects is almost reached! We look forward to recruiting the last patients and shortly thereafter publishing the first results of this landmark trial. We thank you for your excellent work and support!

### Recruitment status (data on 4 March 2019)

Country	N° of open sites	N° of enrolling sites	N° of randomised subjects
France	7	7	80
Italy	6	4	27
Netherlands	4	4	26
Spain	4	4	11
Switzerland	3	1	7
United Kingdom	4	4	43
<b>Total</b>	<b>28</b>	<b>24</b>	<b>194</b>

### Accrual RACE trial



### RACE-ing forward

- Expected last patient in: April 2019
- Last patient 3m FU visit: July 2019
- Last patient last visit: April 2021
- First abstract (primary endpoint 3m FU): ASH 2019
- Abstract presentation: ASH 2021

### Contact

#### Questions about RACE?

Contact Sofie Terwel at: +31 71 526 1183 or [RACEtrial@lumc.nl](mailto:RACEtrial@lumc.nl)

#### New Clinical Trial or Non-Interventional Study Proposals?

Contact Marianne Mol (CTO manager) at: +31 71 526 3953 or [marianne.mol@ebmt.org](mailto:marianne.mol@ebmt.org)



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