

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 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 at 3 months since start of treatment in naive severe AA patients.

CR is defined as: Hb>10 g/dL, ANC>1,000/ μ L and Platelets>100,000 μ L

Country Status (data per 7 March 2017)

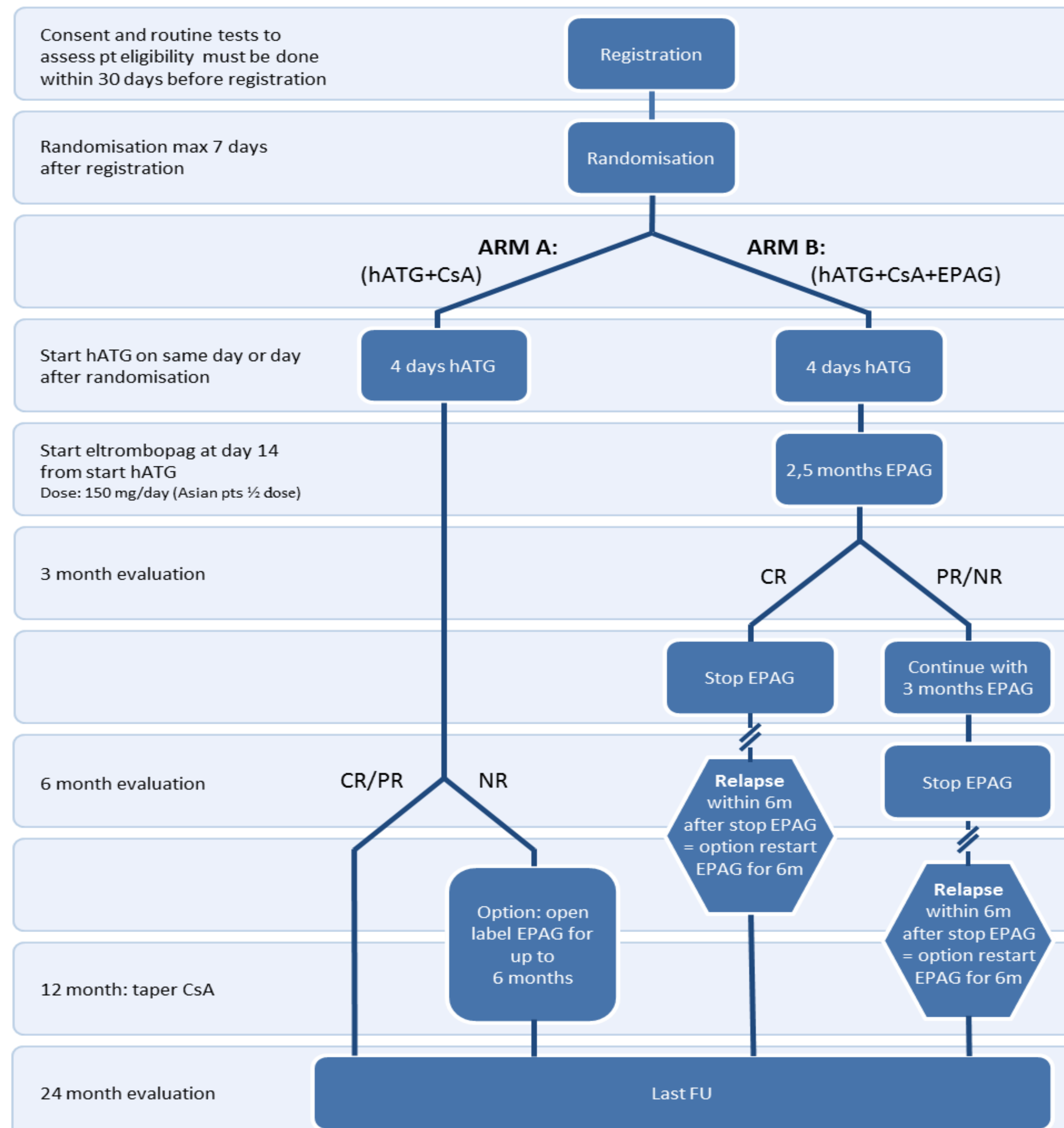
Country	N° of sites (N° of open sites)	N° of Patients
France	8 (6)	37
Germany	5 (0)	0
Italy	9 (3)	4
Netherlands	4 (3)	11
Spain	6 (1)	1
Switzerland	2 (1)	2
United Kingdom	5 (4)	14
Total	39 (18)	69

The RACE trial is currently on hold in Germany, awaiting marketing authorisation approval of ATGAM as first line aplastic anaemia treatment in Europe.

Main Inclusion Criteria

- Diagnosis of severe or very severe aplastic anemia, defined by:
 - At least two of the following:
 - Absolute neutrophil counts $<0,5 \times 10^9/L$ (severe) or $<0,2 \times 10^9/L$ (very severe)
 - Platelets counts $<20 \times 10^9/L$
 - Reticulocyte counts $<60 \times 10^9/L$
 - Hypocellular bone marrow ($<30\%$ cellularity without evidences of fibrosis or malignant cells)
- Male or female age ≥ 15 years

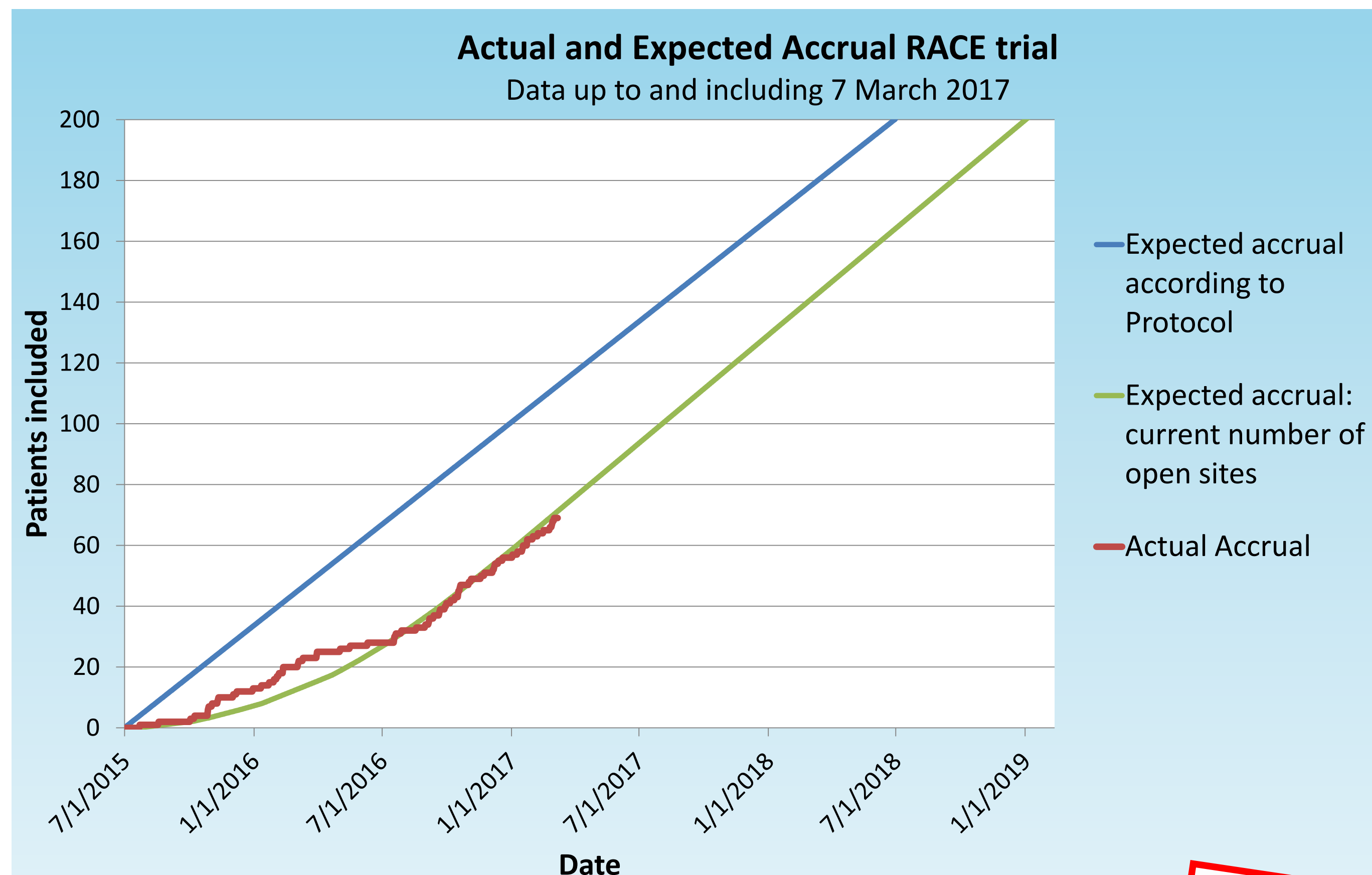
Treatment schema



Legenda:
EPAG = Eltrombopag
hATG = ATGAM
CsA = Cyclosporin

Note 1: time is not depicted linearly. With || we indicate a variable time span between 2 weeks and 6 months after stop EPAG treatment.
Note 2: patients with NR at 6 months FU are considered treatment failures and should receive rescue treatment chosen by PI. Only patients in arm A are eligible for 3 up to 6 month EPAG as salvage treatment within the RACE trial.

Accrual



Join our training session

Monday 27 March at the EBMT Annual Congress in Marseille.
Location: lecture hall Samena (part of the DM programme)
15:15-15:40 - State of the art on immunosuppressive treatment in AA
15:40-16:00 - Status of the RACE trial
16:00-16:30 - Break
16:30-17:00 - RACE specific training, including new CRFs and SAE reporting

Meet the team

Visit us at the EBMT booth on Monday and Tuesday from 12:45 to 14:15.
You can also contact us by e-mail RACEtrial@lumc.nl or call us on +31 71 526 1988