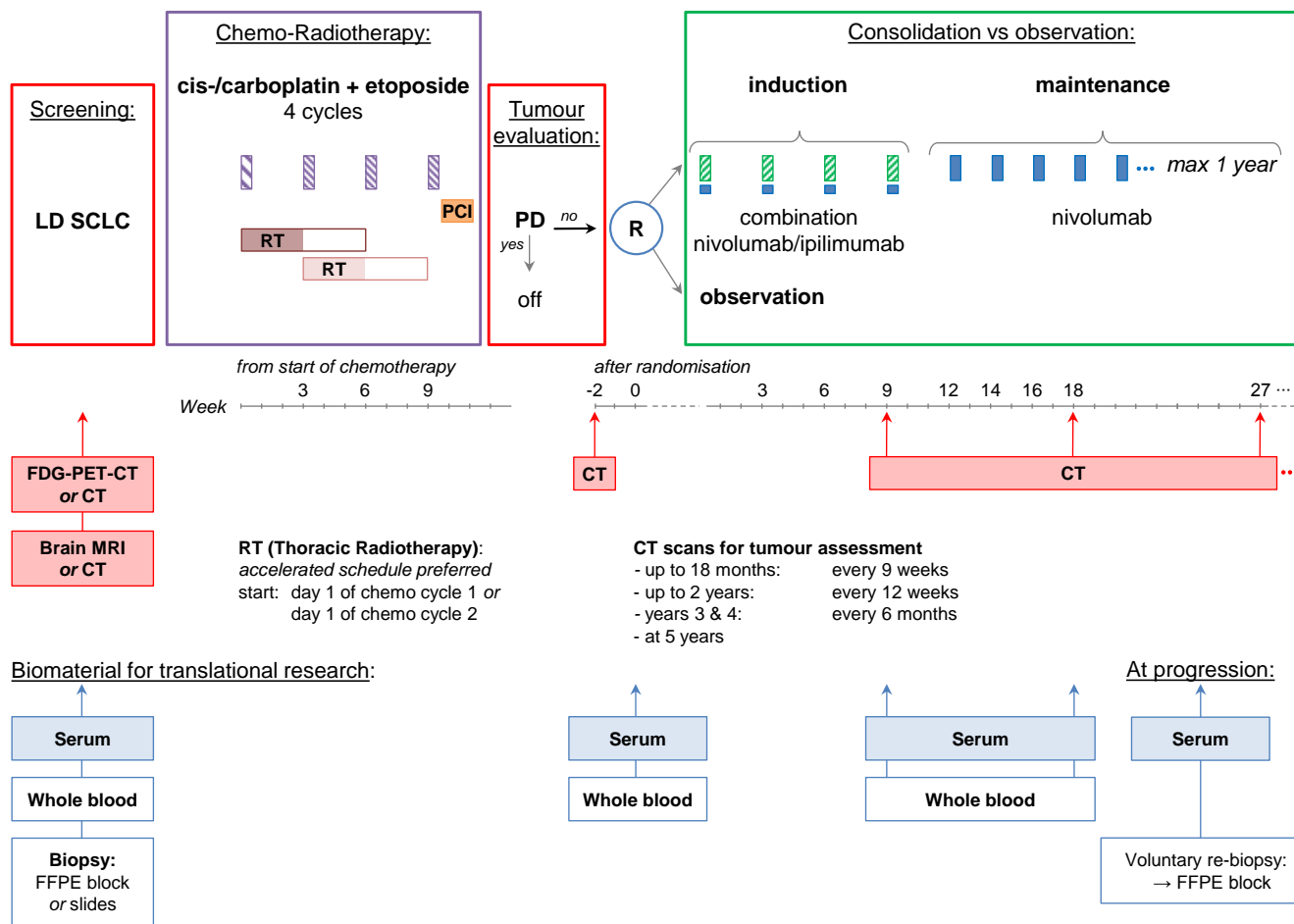




ETOP / IFCT 4-12 STIMULI Trial

Rolf Stahel

2 | ETOP / IFCT 4-12 STIMULI: A randomised open-label phase II trial of consolidation with nivolumab and ipilimumab in limited-stage SCLC after chemo-radiotherapy



Co-primary endpoints

- Progression-free survival and overall survival

Sample size

- 260 randomized patients

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- **Population:** limited-stage SCLC
- **Design:** Open-label, randomised, two-arm, phase II international multi-centre clinical trial with early interim analysis for safety
- **Primary endpoints:** PFS and OS
- **Planned sample size:** 260 patients randomised, approximately 325 enrolled
- **Randomisation:** Nivolumab and ipilimumab consolidation vs observation
- **Stratification:**
 - by twice-daily vs once-daily radiotherapy
 - PET-CT done vs not done.

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Objectives

- To evaluate whether patients treated with
 - chemo-radiotherapy and prophylactic cranial irradiation followed by nivolumab and ipilimumab consolidation have better outcome (PFS and OS) compared to
 - patients treated with chemo-radiotherapy and prophylactic cranial irradiation without nivolumab and ipilimumab consolidation
- To evaluate secondary measures of clinical efficacy including
 - objective response rate (ORR) and
 - time to treatment failure
- To assess the safety and the tolerability of the treatment in both arms

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Participating Sites and Countries

STIMULI is currently activated in 7 countries

France (IFCT):	26 sites
Spain (SLCG):	10 sites
Germany:	7 sites
Switzerland:	2 sites
UK:	1 out of 3 sites
Netherlands:	2 sites
Belgium:	1 site

Currently 49 out of 51 sites activated

Participation of Australian sites in preparation



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Accrual Status May 2017

Country	Number of Patients	
	Enroled	Randomised
France	52	32
Spain	34	16
Switzerland	8	6
Belgium	2	0
Germany	7	0
Netherlands	3	2
UK	--	--
Total	106	56

Thank you for listening!

