



Washington, DC October 5, 2015

SWIFT PRIME Update

J. Saver, M. Goyal, A. Bonafé, H. Diener, E. Levy, V. Mendes-Pereira, G. Albers, C. Cognard,
D. Cohen, W. Hacke, O. Jansen, T. Jovin, H. Mattle, R. Nogueira, A. Siddiqui, D. Yavagal,
T. Devlin, D. Lopes, V. Reddy, R. du Mesnil de Rochemont and R. Jahan for the
SWIFT PRIME Investigators

Study Methods

Objective

To compare the functional outcomes in AIS subjects treated with either IV t-PA alone or IV t-PA in combination with Solitaire device

Target Vessel

Intracranial ICA, M1 MCA, and carotid terminus

Hypothesis

Combined treatment with IV t-PA and Solitaire device will result in lower mRS scores than treatment with IV t-PA alone

Sample Size

Maximum 833, expected 477
5 interim analyses,
1st at 200 evaluable

Design

Global, multi-center, prospective, randomized, open, blinded endpoint (PROBE) IDE Study

Population

- AIS with large vessel occlusion
- Able to be treated with Solitaire device within 6 hours of stroke onset
- Received IV t-PA within 4.5 hours of stroke onset

Randomization

1:1
IV t-PA alone vs. Solitaire + IV t-PA

Sites

Up to 90 centers total
(50 US & 40 Europe)

Follow-up Visits

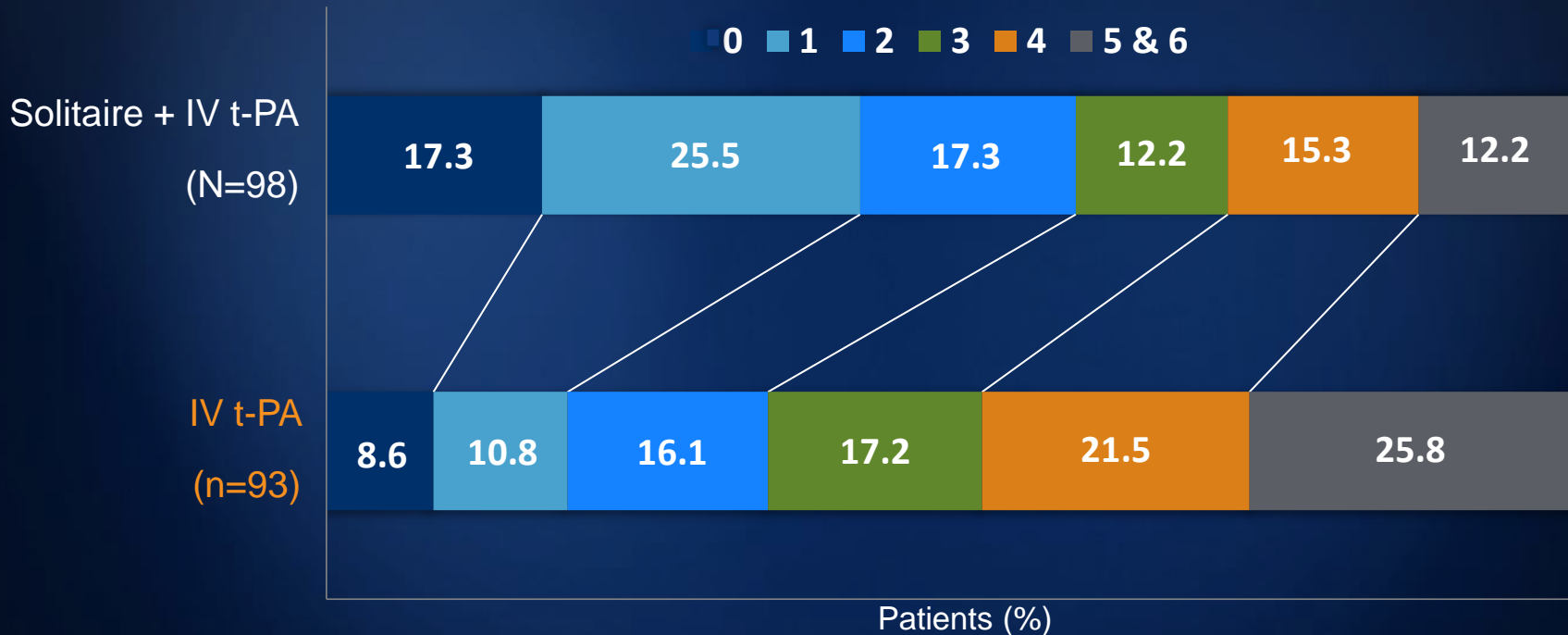
Follow-up: 27 ±6 hours, 7-10 Day/Discharge, 30 Day, 90 Day

Primary Endpoint

Blinded evaluation of modified Rankin Scale (mRS) Score at 90 day

Primary Endpoint

Modified Rankin Scale Score **$p=0.0002$** (Cochran-Mantel-Haenszel p value)



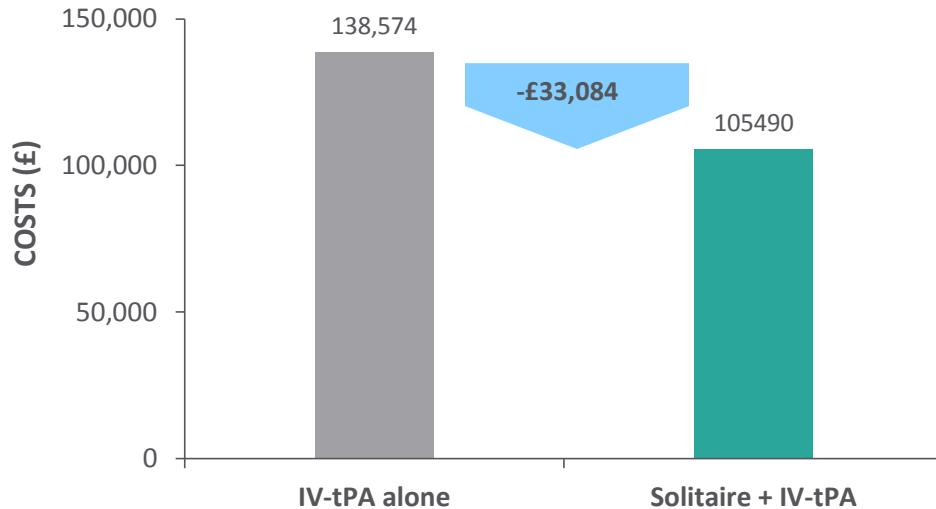
	Solitaire + IV t-PA	IV t-PA	
Functional independence (mRS 0-2) at 90D	59 (60.2%)	33 (35.5%)	$p < 0.001$
mRS score at 90 days – median (IQR) [N]*	2 (1 - 4) [98]	3 (2 - 5) [93]	

SWIFT PRIME Cost-Effectiveness Analysis Using UK Health System Data

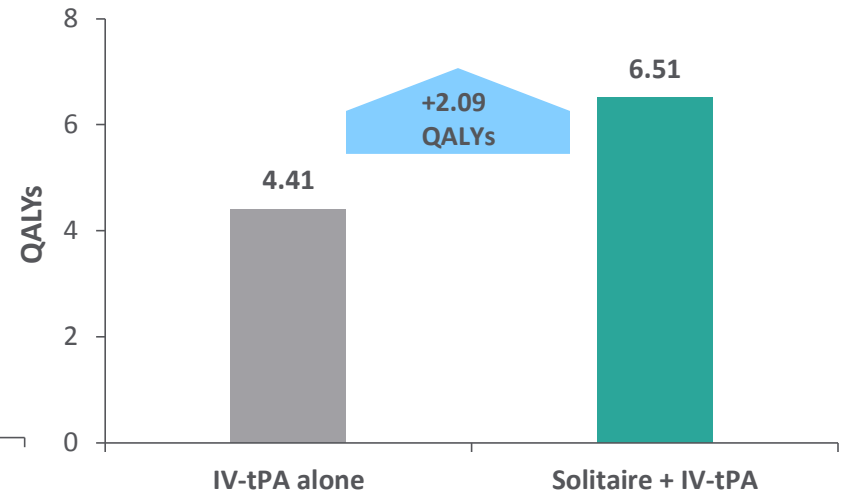
Solitaire+ IV-tPA is improves outcomes AND saves costs IV-tPA alone

Over 20 years the average cost saving is £33,084 and QALYs gained 2.09.

COST PER PATIENT IN THE UK OVER 20 YEARS, BY TREATMENT¹

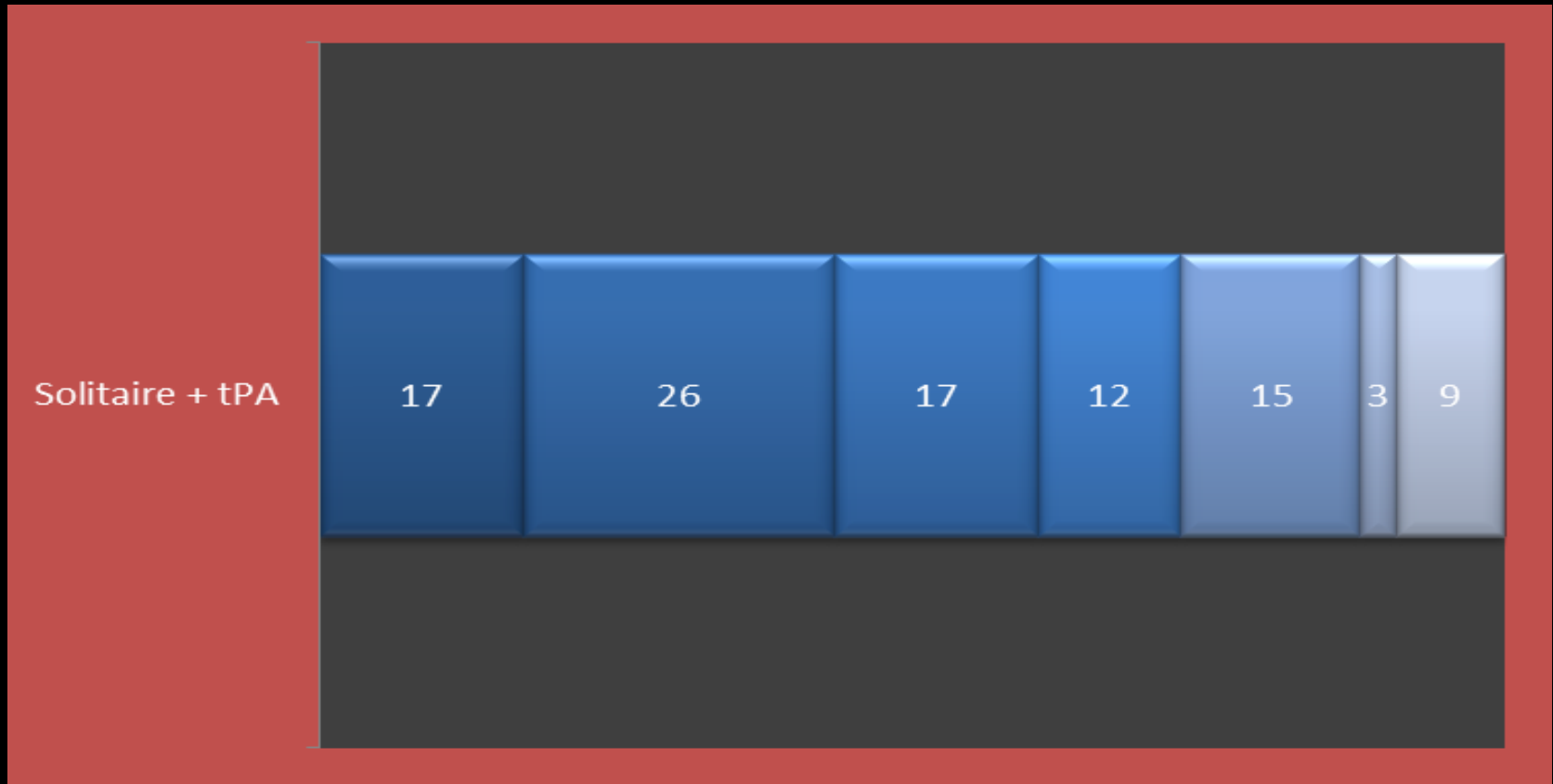


TOTAL QALYs GAINED PER PATIENT IN THE UK OVER 20 YEARS, BY TREATMENT¹



Are We Done Yet?

SWIFT PRIME Thrombectomy Outcomes

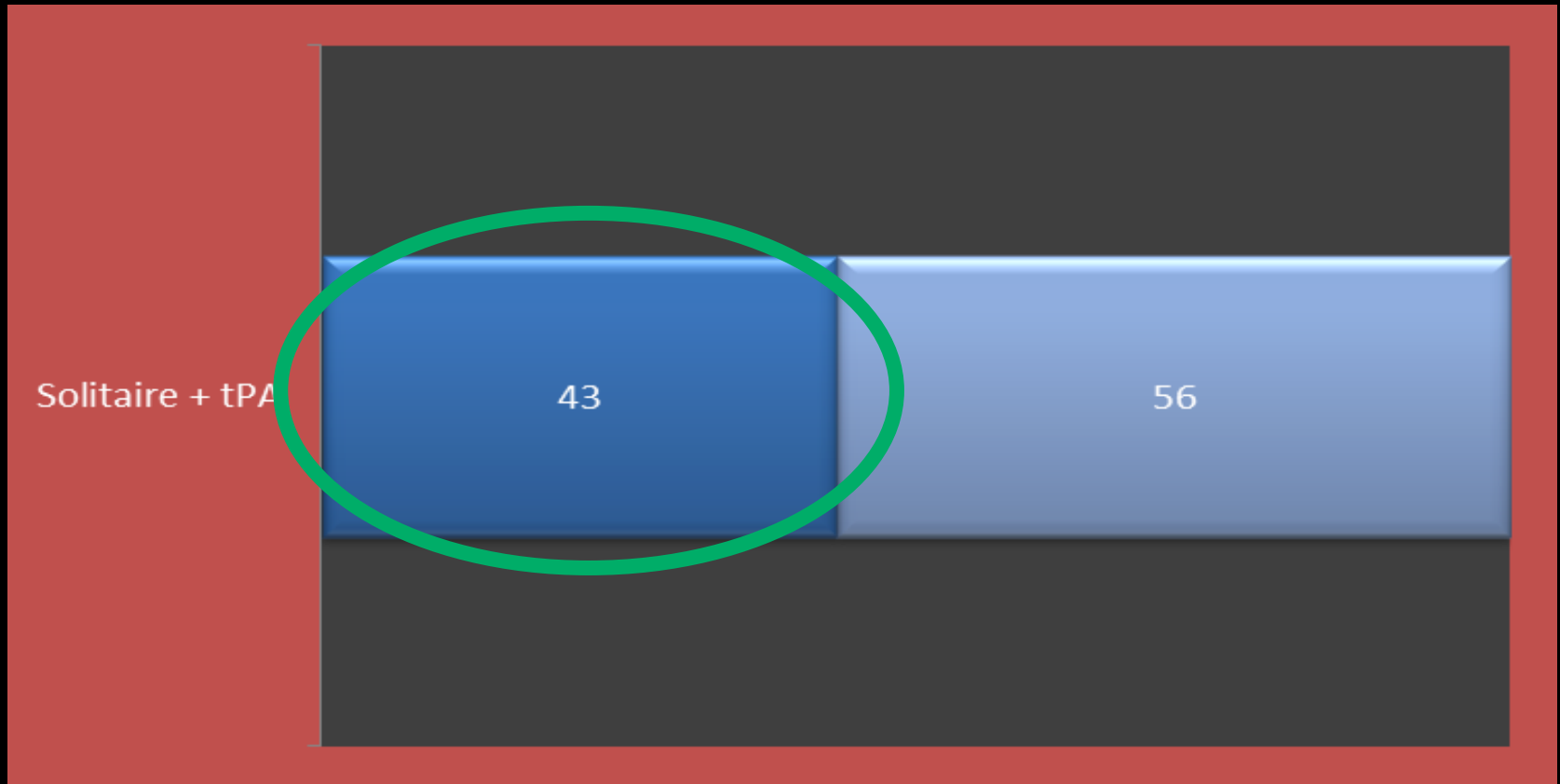


Are We Done Yet?

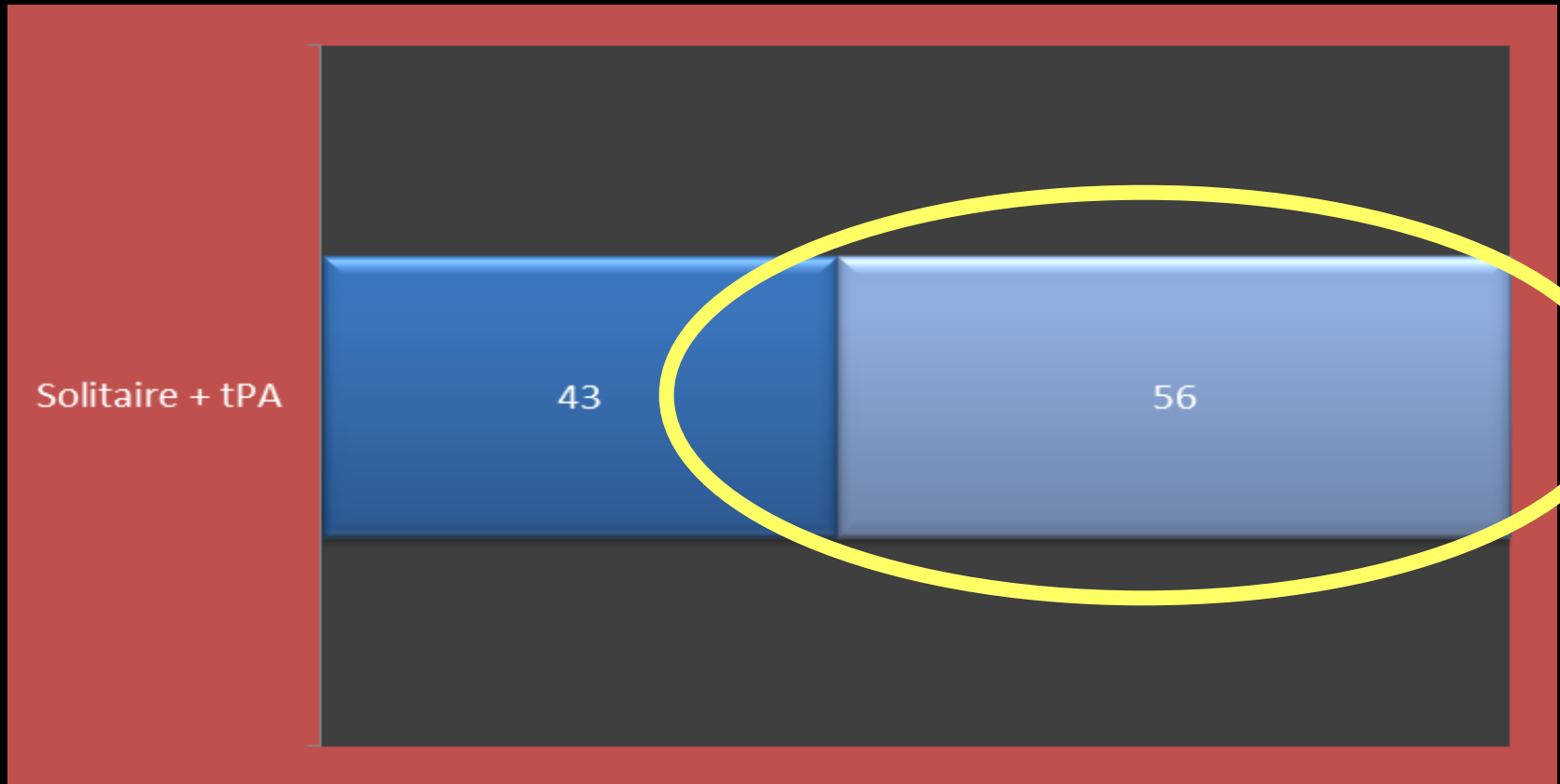
SWIFT PRIME Thrombectomy Outcomes



Are We Done Yet? Nondisabled Outcomes



Are We Done Yet? Disabled or Dead



SWIFT PRIME Lessons for Next Generation of Clinical Trials

Intervention Type	Special Trial Aspects	Example Comparisons	Target Patients
Reperfusion Strategies	Active Comparator	IVT+ERT vs ERT alone	ICA occlusions
		IVT+ERT vs IVT alone	Distal M2 occlusions
Systems of Care	Cluster randomization	EMS routing – PSCs first versus CSCs first	Severe deficits
Prehospital Neuroprotection	ED imaging endpoints	NA1, hypothermia, RIPC, NTG vs control	EMS transported patients
Deter Reperfusion Injury	IA admin	Free radical scavengers vs control	Post-successful reperfusion
New Devices	- Reperfusion 2b/3 primary surrogate endpoint	Device A vs B	Large artery occlusions
All	Speed	EFIC, Ambulance pre-consent, Short form consent	Large artery occlusions
All	More important + sensitive endpoints	--Ordinal mRS --Linear using item banks	Large artery occlusions

[US Enrolling Centers]

101	UCLA / Ronald Reagan UCLA Medical Center	Starkman
102	Oregon Health and Science University (OHSU)	Clark
103	University of Pittsburgh Medical Center	Reddy
104	University of Buffalo Neurosurgery, Buffalo General Hospital	Siddiqui
105	University of Miami Jackson Memorial Hospital Chattanooga Center for Neurologic Research /	Yavagal
106	Erlanger Hospital	Devlin
109	Hennepin County Medical Center	Jagadeesan
110	Medical College of Wisconsin Froedtert Hospital West	Fitzsimmons
111	Maine Medical Center	Ecker
113	Ohio Health Research Institute / Riverside Methodist Hospital	Budzik
116	Florida Hospital	Acosta
117	SUNY Upstate Medical University	Deshaiies
118	ProMedica Toledo Hospital	Jumaa
120	Central Baptist	Ramsey
121	Cleveland Clinic	Hussain
122	West Virginia University	Carpenter
123	Providence Brain and Spine Institute	Deshmukh
124	University of Massachusetts Medical Center	Puri
125	Emory University / Grady Medical Center	Nogueira
126	Rush University Medical Center	Lopes
129	Saint Luke's Hospital of Kansas City	Martin
130	St. Jude Medical Center	Farid
134	Valley Baptist Medical Center	Hassan
135	Tenet Hospital System	Malek

[EU Enrolling Centers]

201	CHU Montpellier - Hôpital Gui de Chauliac	Bonafé
203	Universitätsklinikum Kiel	Jansen
204	Hospital Clinico Universitario de Valladolid	Arenillas
206	Klinikum der Johann Wolfgang Goethe-Universität – Frankfurt	du Mesnil de Rochemont
207	Kantonsspital Aarau	Remonda
212	Universitätsklinikum Essen	Weimar
213	Rigshospitalet – Copenhagen	Hansen
214	Klinikum Bremen-Mitte	Papanagiotou
216	Universitätsklinikum Christian Doppler Klinik Salzburg	Killer-Oberpfalzer
218	Universitätsklinikum Heidelberg	Ringleb
220	Klinikum Dortmund	Reimann
224	Universitätsklinikum Hamburg-Eppendorf	Brekenfeld
225	Klinikum rechts der Isar der TU Munchen	Prothmann
228	Landes - Nervenlinik Wagner-Jauregg	Haring
229	Aarhus University Hospital	Andersen

Study Organization



Executive Committee

Jeffrey Saver, MD
Mayank Goyal, MD
Prof. Alain Bonafé
Prof. Hans Diener
Elad Levy, MD
Vitor Mendes-Pereira, MD
Reza Jahan, MD

Steering Committee

Gregory Albers, MD
Prof. Christophe Cognard
David Cohen, MD
Prof. Werner Hacke
Prof. Olav Jansen
Tudor Jovin, MD
Prof. Heinrich Mattle
Raul Nogueira, MD
Adnan Siddiqui, MD
Dileep Yavagal, MD

SWIFT PRIME

Data Safety Monitoring Board

Prof. Rüdiger Von Kummer
Wade Smith, MD
Prof Francis Turjman
Scott A. Hamilton, PhD
Richard Chiacchierini, PhD

Clinical Events Committee

Arun Amar, MD
Yince Loh, MD
Nerses Sanossian, MD

Core Labs

iSchemaView
Bioclinica

[SWIFT PRIME]

Thank you!