

START Newsletter

The Strategic Timing of AntiRetroviral Treatment – An INSIGHT Trial
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START ACCRUAL AT 2000

On 3 February 2012, START accrual reached 2000, halfway to the current goal of 4000 participants. Congratulations to all site staff who have worked hard to reach this critical milestone! Special kudos to Site Coordinator Carina Yoshida and the team at Projeto Praça Onze at St. Francis Hospital, Rio de Janeiro, for enrolling the 2000th participant!

RECRUITMENT UPDATE

The START Study will be conducted at 239 sites in 35 countries on six continents. Cumulative and recent accrual at the 217 sites open to the study is shown in Table 1.

Table 1: START Countries, Open Sites, and Accrual

Country	Open Sites	Total Accrual As of 13 Feb	Accrual Last 2 Mo
Argentina	8	102	8
Australia	15	61	7
Austria	2	1	0
Belgium	4	72	8
Brazil	5	191	16
Chile	1	57	2
Czech Republic	2	6	1
Denmark	4	27	2
Estonia	1	0	0
Finland	1	17	0
France	12	92	3
Germany	17	236	16
Greece	6	54	6
Ireland	2	1	1
Israel	1	15	2
Italy	1	17	2
Luxembourg	1	2	2
Mali	1	28	1
Morocco	1	30	0
Norway	1	9	5
Peru	5	91	11
Poland	3	62	2
Portugal	3	9	8
South Africa	2	129	2
Spain	13	117	5
Sweden	2	0	0
Switzerland	5	24	1
Thailand	9	96	13
Uganda	2	4	0
United Kingdom	20	176	32
United States	67	302	20
TOTAL	31	217	176

Congratulations to sites in Austria, Portugal, Spain, Sweden, and Thailand that have recently opened to START! Twenty-two remaining sites in Argentina (4), Brazil (2), India (3), Israel (1), Italy (1), Malaysia (1), Mexico (1), Nigeria (1),

Portugal (1), Spain (2), South Africa (3), and the US (2) plan to open by April.

TOP ENROLLING SITES

Congratulations to the following 11 sites for achieving the top enrolment into START in December and January:

Table 2: Top 11 Enrolling START Sites in Past 2 Months

Rank	Site and Country	Accrual	
		Dec + Jan	As of 13 Feb
1	Hospital Escola São Francisco de Assis – UFRJ, Rio de Janeiro, Brazil	8	110
1	Instituto de Infectologia Emilio Ribas – IIER, São Paulo, Brazil	8	81
1	Chulalongkorn University Hospital, Bangkok, Thailand	8	65
2	Hospital Joaquim Urbano, Porto, Portugal	6	7
3	Klinik I für Innere Medizin der Universität zu Köln, Cologne, Germany	5	34
3	Khon Kaen University, Srinagarind Hospital, Khon Kaen, Thailand	5	29
3	Oslo University Hospital, Ullevål, Oslo, Norway	5	9
4	Institute of Tropical Medicine, Antwerp, Belgium	4	38
4	Royal Bournemouth Hospital, Bournemouth, UK	4	6
4	Belfast Health and Social Care Trust (RVH), Belfast, N Ireland	4	4
4	Hippokratia University General Hospital of Athens, Greece	4	4

NEW SITE ACCRUAL TARGETS

The START Co-Chairs recently asked each ICC to update site accrual targets through the end of December 2012. The new figures are modestly reduced from previous estimates, and still show that the target of 4000 participants accrued into START is well within reach before the end of 2012.

DATA AND SAFETY MONITORING BOARD

The START Data and Safety Monitoring Board (DSMB) will meet again in early May 2012 for a comprehensive safety and efficacy review. The last DSMB review was in April 2011. The primary endpoints of START are AIDS and serious non-AIDS conditions, including deaths. As usual, the open report submitted to the DSMB as well as the summary report produced by the DSMB will be posted on the INSIGHT website after the review.

International Network for Strategic Initiatives in Global HIV Trials

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SUBSTUDY ENROLMENT

Accrual into the START Genomics, Informed Consent, Neurology and Arterial Elasticity substudies remains on target with high co-enrolment rates. Accrual into the Pulmonary substudy is progressing with an increasing co-enrolment rate. Bone Mineral Density substudy sites have just begun to accrue and are doing so at a high co-enrolment rate. The Liver Fibrosis Progression substudy has just enrolled its first 3 participants at Queen Elizabeth Hospital Woolwich, UK. Congratulations!

Table 3: START Substudies – Goals, Accrual, Co-Enrolment

START Substudy	Goal	Accrual As of 9 Feb	Co-Enrolment Rate
Genomics	n/a	1418	95%
Informed Consent	n/a	1972	n/a
Neurology	600	557	75%
Arterial Elasticity	300	185	71%
Pulmonary	1000	366	52%
Bone Mineral Density	400	61	87%
Liver Fibrosis	990	3	60%

BONE MINERAL DENSITY SUBSTUDY

The Bone Mineral Density substudy will obtain baseline and annual hip and lumbar spine DXA scans on 400 START Study participants co-enrolled at 41 sites in 12 countries on 6 continents. DXA scan images are obtained at 17 Radiology Centers and read centrally at the University of California San Francisco.

The hypothesis of the substudy is that bone mineral loss will be greater in those randomized to early ART, since ART has been linked to bone loss. Evidence is strongest for tenofovir and some protease inhibitors. The substudy is open to all at participating sites, except for those currently receiving treatment for osteoporosis and anyone in whom valid BMD measurements by DXA scan are not possible.

The substudy has opened at 33 sites and has enrolled 62 participants to date. Sites in Brazil (2), India (1), Italy (1), Spain (1), South Africa (1), and the US (2) will soon open along with Radiology Centers in Rome, Italy; Seville, Spain; Pune, India; and Johannesburg, South Africa.

There is great community interest on the effects of antiretroviral therapy on bone. The START BMD substudy will provide important data on bone mineral loss and early versus deferred ART.

The substudy is supported by funding from the National Institute for Arthritis and Musculoskeletal Diseases (NIAMS) at NIH, Bethesda, MD, US.

NEW START PARTICIPANT WEBSITE AND VIDEO

A new START participant-oriented website and promotional video has recently gone live at www.theSTARTstudy.org. Supported by a supplement from the Division of AIDS/NIAID/NIH to help boost accrual at U.S. sites, all sites in START are welcome to use these materials, which are available in English and, in some cases, Spanish. The 8-minute video is professionally produced, and includes two START participants sharing why they joined the study, as well as comments by clinicians, former research participants, and HIV advocates on why START – and clinical research in general – is important. Sites may need IRB/Ethics Committee approval before using these materials for study recruitment. The video is available in both English and Spanish (with subtitles) and can also be seen on YouTube (www.youtube.com, search “The START Study”). We encourage sites to share these links widely with your professional and community partners.

INSIGHT INVESTIGATOR MEETING AT CROI

INSIGHT invites those attending CROI in Seattle, WA, USA, to an investigator meeting, on Monday, 5 March 2012, from 12:30 – 15:30 at the Seattle Marriott Waterfront Hotel. A buffet lunch will be served at 11:30. Please register at <http://www.insight-trials.org/registration> before 27 Feb.

The presentations at the meeting will include an overview of INSIGHT abstracts at CROI, a Scientific Steering Committee update, an update on START and the substudies, and a panel presentation on the importance of adherence to study arm and completeness of event surveillance to ensure the success of START.

NEUROLOGY SUBSTUDY ALMOST ACCRUED

Neurology substudy accrual is nearly complete with 561 of 600 (94%) participants enrolled to date. The substudy team will be sending participating sites more information soon about closure of the substudy to accrual, which we expect will occur by the end of April 2012.

INSIGHT WEB REPORTS

The Reports section for START on the INSIGHT website will soon be reorganized to make for easier navigation and to highlight items such as data queries and missing CRFs that require immediate action by a site. We will notify you when this user-friendly web update is going live.