

# EuroSIDA Cohort 10 Newsletter

July 2015



## ANNOUNCEMENTS

### Dear EuroSIDA Cohort 10 Study Investigators,

To be at the forefront of investigating the treatment benefits and adverse effects of the new HCV treatment, the EuroSIDA steering committee decided in 2014 to enroll a new cohort of approximately 5,000 HIV/HCV co-infected patients. The support for this new cohort 10, the largest expansion of EuroSIDA ever, has been tremendous. Initially 69 existing, and two new (Tbilisi and Poznan), EuroSIDA centers showed interest in participating. Since the first patient was enrolled in May 2014, seven centers have agreed to recruit patients into the new cohort, including two existing centers, and five new EuroSIDA centers in Madrid, Valencia, Vilnius, Samara and Lviv. Most EuroSIDA countries are well represented in cohort 10.

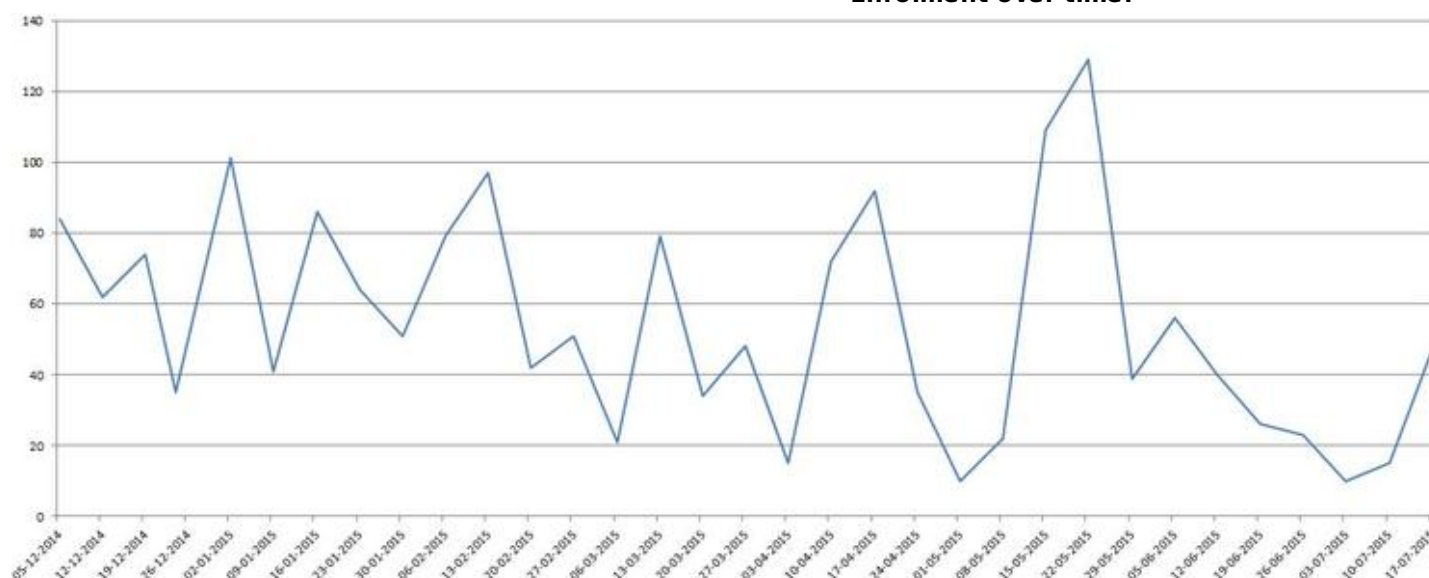
### Enrolment status

As of 15 July 2015, 3,347 patients, from 65 centers, have been enrolled in cohort 10. The five new centers are just about to enroll their first patients. The enrolment over time is shown in the figure, and the enrolment status at country and site level in the table below. Thirty-five centers have already met their initial enrolment target. Sixteen of these have subsequently increased their enrolment target, and eight centers have met their second target.

The plan is to continue enrolment until the end of 2015. Although enrolment has been slower than first anticipated, we still think it is realistic to enroll a total of 5,000 patients. We are aware that there is often little time in the outpatient clinic to inform patients about the study and obtain informed consent. As a way to increase enrolment, one center has introduced an opt-out strategy where patients receive written information about the study when they arrive at the outpatient clinic, and they will be included in the study unless they say no.

For the coordinating centre to be able to track the enrolment proces, we encourage you to please complete enrolment forms in the 'status' section once all enrolment data has been entered.

**Enrolment over time:**



### Entering data in REDCap

The initiation of cohort 10 also coincided with the transition from data collection on paper forms, to use of the electronic data collection software, REDCap. It is our impression that most have been satisfied with using REDCap, although some of you have found REDCap more time consuming than the old paper forms. Apart from saving resources on staff at the coordinating centre, and on paper and shipment, electronic data capture should also reduce the risk of incorrect data. The checking and monitoring of data done so far, confirm that the data are of high

quality. Please let us know if you have suggestions about how to improve data collection.

## EuroSIDA and D:A:D

EuroSIDA participates in the D:A:D multicohort study. The sites are therefore asked to fill out D:A:D event forms when certain clinical criteria are met. However, patients enrolled in EuroSIDA cohort 10 are not included in D:A:D, and D:A:D event forms should therefore not be completed for cohort 10 patients. For patients enrolled in earlier EuroSIDA cohorts there are no changes with regards to D:A:D.

## Funding of cohort 10

EuroSIDA has funding from an EU grant for enrolment and two years of follow up for 2500 patients. Remaining fundings have been requested from pharmaceutical companies. So far, funding has been obtained from Bristol-Meyers Squibb, while negotiations with other pharmaceutical companies are still ongoing.

## Cohort 10 at the EACS conference

In conjunction with the EACS conference in Barcelona, there will be a EuroSIDA investigator meeting on Friday 23rd of October at 7.30 in Class room 129+130 where we will present an update on cohort 10. Furthermore, an abstract describing the baseline characteristics of all HIV/HCV co-infected patients under active follow up in EuroSIDA will be submitted to the conference.

We wish you all a great summer and thank you for your continuous fruitful collaboration!

## Cohort 10 enrolment progression at country and site level:

level:

Hospital	Country	Target	Enrolled on 15/07 2015	Percentage	Hospital	Country	Target	Enrolled on 15/07 2015	Percentage
CHU Saint-Pierre	Belgium	130	45	34,615	Ben Ari Institute of Clinical Immunology	Israel	30	30	100
University Ziekenhuis Gent	Belgium	25	25	100	Rambam-Health Care Campus	Israel	5	0	0
Hvidovre Universitets Hospital	Denmark	110	58	52,727	University Hospital Zürich	Switzerland	300	300	100
Rigshospitalet	Denmark	50	14	28	Hopital Cantonal Universitaire	Switzerland			
Odense Universitetshospital Forskningsenheden	Denmark	10	8	80	Centre hospitalier Universitaire Vaudois	Switzerland			
Skejby Sygehus	Denmark	25	13	52	University Hospital Bern	Switzerland			
Roskilde Sygehus	Denmark	0	0		University Hospital Basel	Switzerland			
Mortimer Market Centre	United Kingdom	10	0	0	Kantonsspital St. Gallen	Switzerland			
Royal London Hospital	United Kingdom	30	17	56,667	Karolinska University Hospital Huddinge	Sweden	100	100	100
Ridu Edinburgh	United Kingdom	125	71	56,8	Södersjukhuset, Venhälsan	Sweden	105	45	42,857
Royal Free	United Kingdom	55	12	21,818	Oslo Universitetssykehus	Norway	11	10	90,909
Royal Sussex Country Hospital, Brighton	United Kingdom	20	0	0	Medical University Innsbruck	Austria	80	80	100
Helsinki University Central Hospital	Finland	50	50	100	Gomel state Medical University	Belarus	60	50	83,333
the Hôtel-Dieu Hospital	France	20	20	100	GOCGEIOZ (Gomel Regional Centre for	Belarus	70	70	100
CHU Nice Hopital de l' Archet 1	France	15	12	80	Botkin Hospital of Infectious Diseases	Russia	70	60	85,714

Hospital Saint Antoine	France	400	220	55	Centre for HIV/AIDS & and infectious diseases	Russia	89	89	100
Hôpital Necker-Enfants Malades	France	59	79	133,9	Novgorod Centre for AIDS prevention and control	Russia	100	100	100
Medizinische Poliklinik	Germany	20	20	100	Nizhny Novgorod Scientific and Reserach Institute	Russia	45	45	100
University Clinic Hamburg Eppendorf	Germany	30	0	0	Samara State Medical University	Russia	100		0
J.W.Goethe University Hospital	Germany	100	47	47	Szent László Hospital	Hungary	60	60	100
University Hospital Cologne	Germany	50	29	58	The Institute for Infectious & Tropical Diseases	Serbia	30	30	100
University Hospital Bonn	Germany	60	36	60	AIDS center, Faculty Hospital Bulovka	Czech Republic	10	10	100
ICH Study Center	Germany	100	33	33	Charles University Hospital Plzen	Czech Republic	10	4	40
Infectious Diseases, AIDS and Clinical Immunology Research Center , Tbilisi	Georgien	180	57	31,667	Wojewodzki Szpital Zakazny	Poland	50	50	100
St. James Hospital	Ireland	25	25	100	Wojewodzki Szpital Specjalistyczny	Poland	45	45	100
Università degli Studi di Modena	Italy	30	30	100	Pomeranian Academy of Medicine (PAM)	Poland	50	17	34
National Institute for Infectious Diseases	Italy	50		0	Wroclaw University School of Medicine	Poland	50	50	100
Ospedale L. Sacco	Italy	200	186	93	Wojewodzki Szpital Specjalistyczny	Poland	50	41	82
Clinic of infectious and tropical diseases, University of Milan, S.Paolo H	Italy	30	22	73,333	Department of Infectious Diseases, Poznan University of Medical Sciences	Poland	30	10	33,333
Centre Hospitalier de Luxembourg	Luxembou rg	30	30	100	West-Tallinn Central Hospital	Estonia	65	65	100
Hospital Curry Cabral	Portugal	60	28	46,667	Narva AIDS centre	Estonia	30	0	0
Hospital Clinic Universitari de Barcelona	Spain	220	194	88,182	Infectious Diseases Center	Lithuania	50	53	106
Hosp. Universitari Germans Trias i Pujol	Spain	100	72	72	Dr. Victor Babes Hospital	Romania	50	45	90
Hospital de la Santa Creu i Sant Pau	Spain	250	244	97,6	Lviv Regional HIV/AIDS Prevention and Control Center	Ukraine	100		0
Hospital Ramon y Cajal	Spain	80	68	85	University Hospital of Infectious Diseases	Croatia	30	30	100
Hospital Universitario de Araba	Spain	10	3	30	Klinicki centar Univerziteta Sarajevo ( KCUS)	Bosnia & Herzegovina	0		
Hospital La Paz, Madrid	Spain	100		0	University Clinical Centre Ljubljana	Slovenia	13	12	92,308
Hospital General Universitario de Valencia	Spain	100		0	Crimean Republican AIDS centre	Ukraine	150		0
Ichilov Hospital	Israel	40	32	80	Hospital J.M. Ramos Mejia	Argentina	60	46	76,667
							5097	3347	65,7

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