



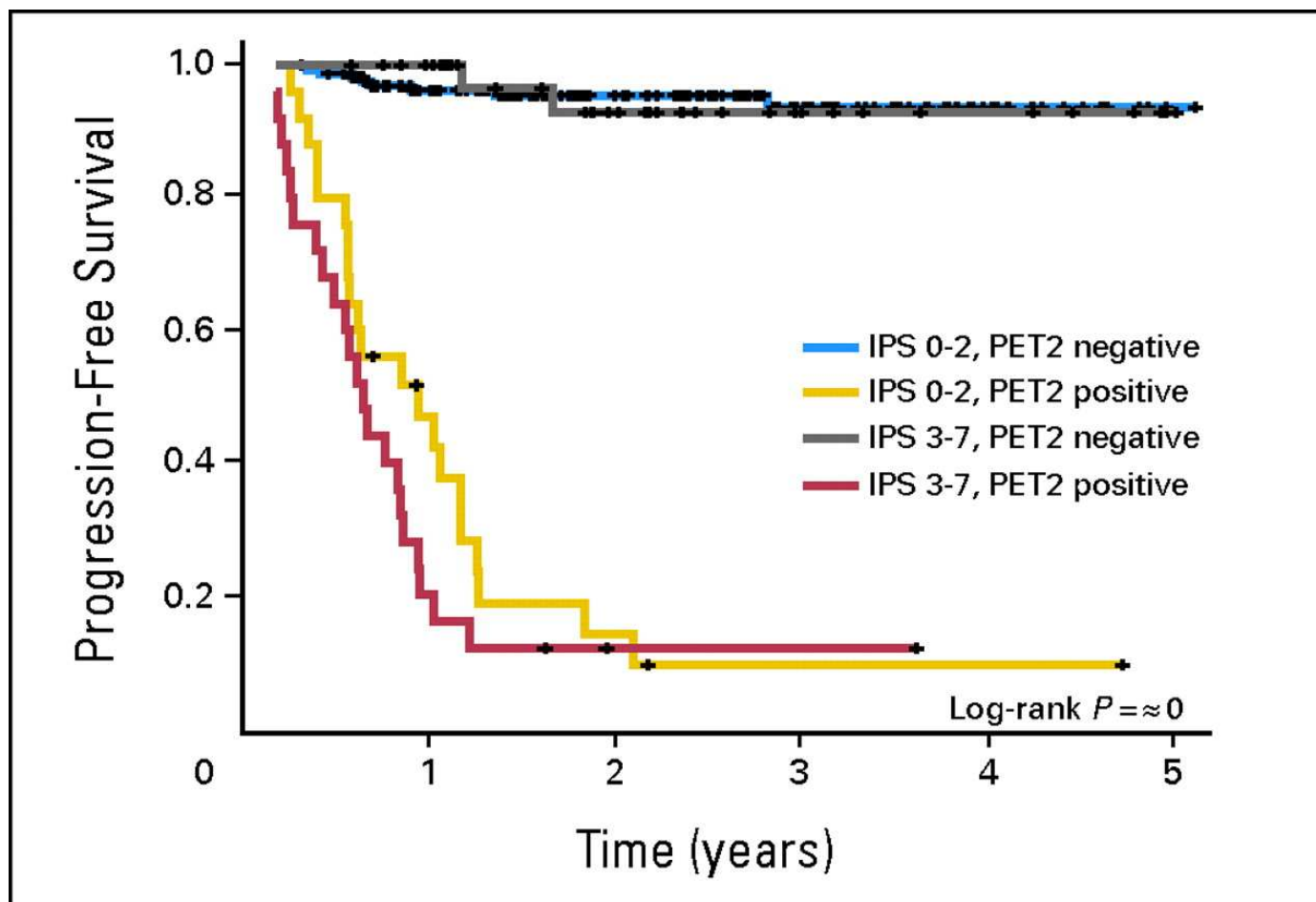
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CRO	Operations Office: Laboratory of Clinical Epidemiology of NEGRISUD Institute

Multicentre clinical study with early treatment intensification in patients with high risk Hodgkin lymphoma, identified as FDG-PET positive after two conventional ABVD courses (HD 0607 study)

Menton, April 9^o, 2010

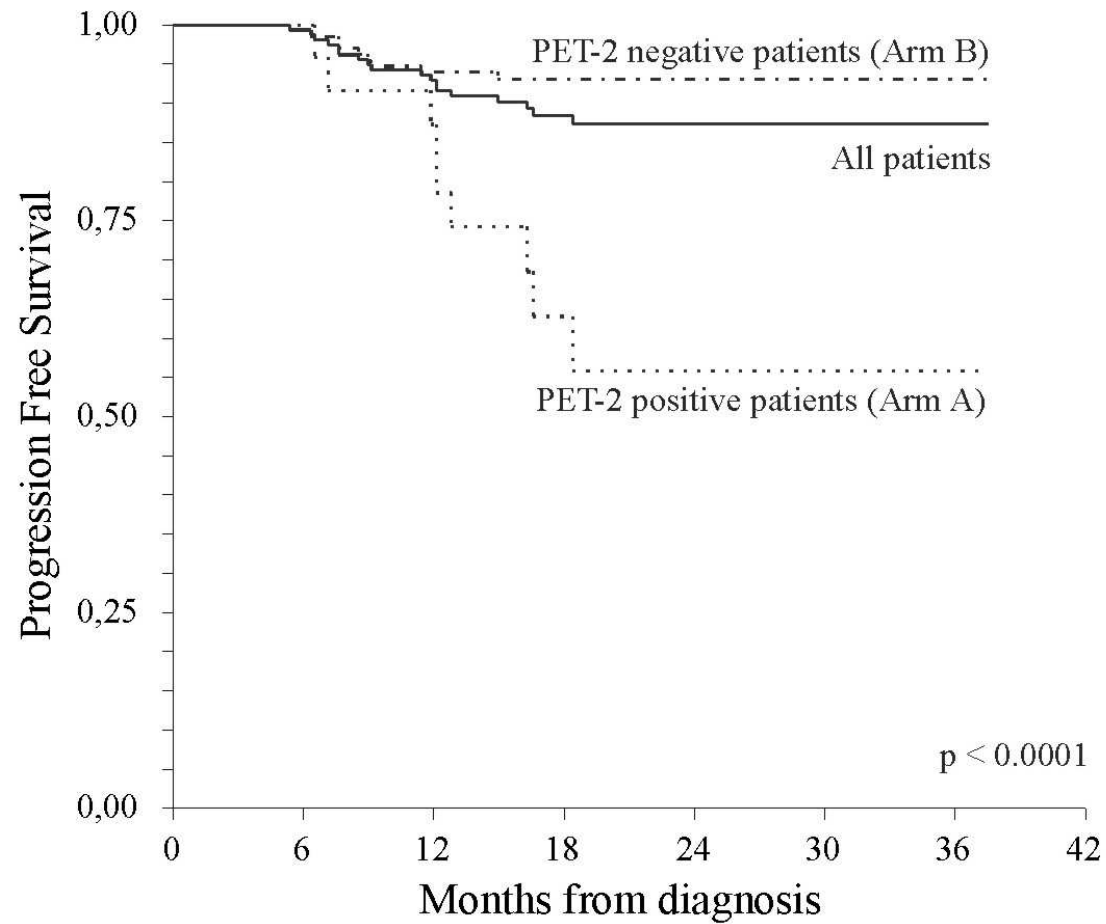
NIH registration code: NCT00795613

Interim PET in ABVD-treated HL patients



Gallamini, A. et al. J Clin Oncol; 25:3746-3752 2007

2-y PFS according to PET results (164 pts)



PET response-adapted clinical trials in advanced-stage HL

1. Positron Emission Tomography (PET)-Adapted Chemotherapy In Advanced Hodgkin Lymphoma (**GITIL HD 0607**).
<http://www.clinicaltrials.gov/ct2/show/NCT00795613>
2. Fludeoxyglucose F 18-PET/CT Imaging in Assessing Response to Chemotherapy in Patients With Newly Diagnosed Stage II, Stage III, or Stage IV Hodgkin Lymphoma (**RATHL**)
<http://www.clinicaltrials.gov/ct2/show/NCT00678327>.
3. High-Dose Chemotherapy and Stem Cell Transplantation, in Patients PET-2 Positive, After 2 Courses of ABVD (**IIL HD 0802**) and Comparison of RT Versus no RT in PET-2 Negative Patients (**IIL HD 0801**).
<http://www.clinicaltrials.gov/ct2/show/NCT00784537>.
4. HD18 for Advanced Stages in Hodgkins LymphomaHD18 for Advanced Stages in Hodgkins Lymphoma. (**GHSG HD 18**)
<http://www.clinicaltrials.gov/ct2/show/NCT00515554>
5. Fludeoxyglucose F 18-PET/CT Imaging and Combination Chemotherapy With or Without Additional Chemotherapy and G-CSF in Treating Patients With Stage III or Stage IV Hodgkin Lymphoma.(**SWOG/CALGB USA Intergroup Trial**)
<http://clinicaltrials.gov/ct2/show/NCT00822120>

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Endpoints

Primary
endpoint

3-year progression free survival (PFS) of the entire cohort of patients .

Secondary
endpoints

- 3-year event free survival (EFS) of all the registered patients, whatever the treatment assigned. Events are deaths from any cause, disease progression, secondary cancer, late serious treatment-related events.

- Feasibility of the program for the entire population of advanced-stage HL patients admitted to GITIL institutions

Inclusion criteria

Inclusion criteria

- Patients with advanced classical Hodgkin Lymphoma according to the WHO classification
- Aged 18-60
- Not previously treated
- Stages IIB to IV B
- All IPS prognostic groups
- Patients who have signed an informed consent form

Exclusion criteria

- Patients aged more than 60.
- Concomitant or previously treated neoplastic disorder less than 5 year before the diagnosis of Hodgkin's lymphoma.
- Psychiatric disorders
- Uncontrolled infectious disease
- Impaired cardiac (EF < 50%) , renal (creatinine clearance < 60 ml/m)HIV,
- HBV DNA, HCV RNA positive markers
- Pregnancy and lactation
- Patients with uncompensated diabetes mellitus and fasting glucose levels over 200 mg/dl

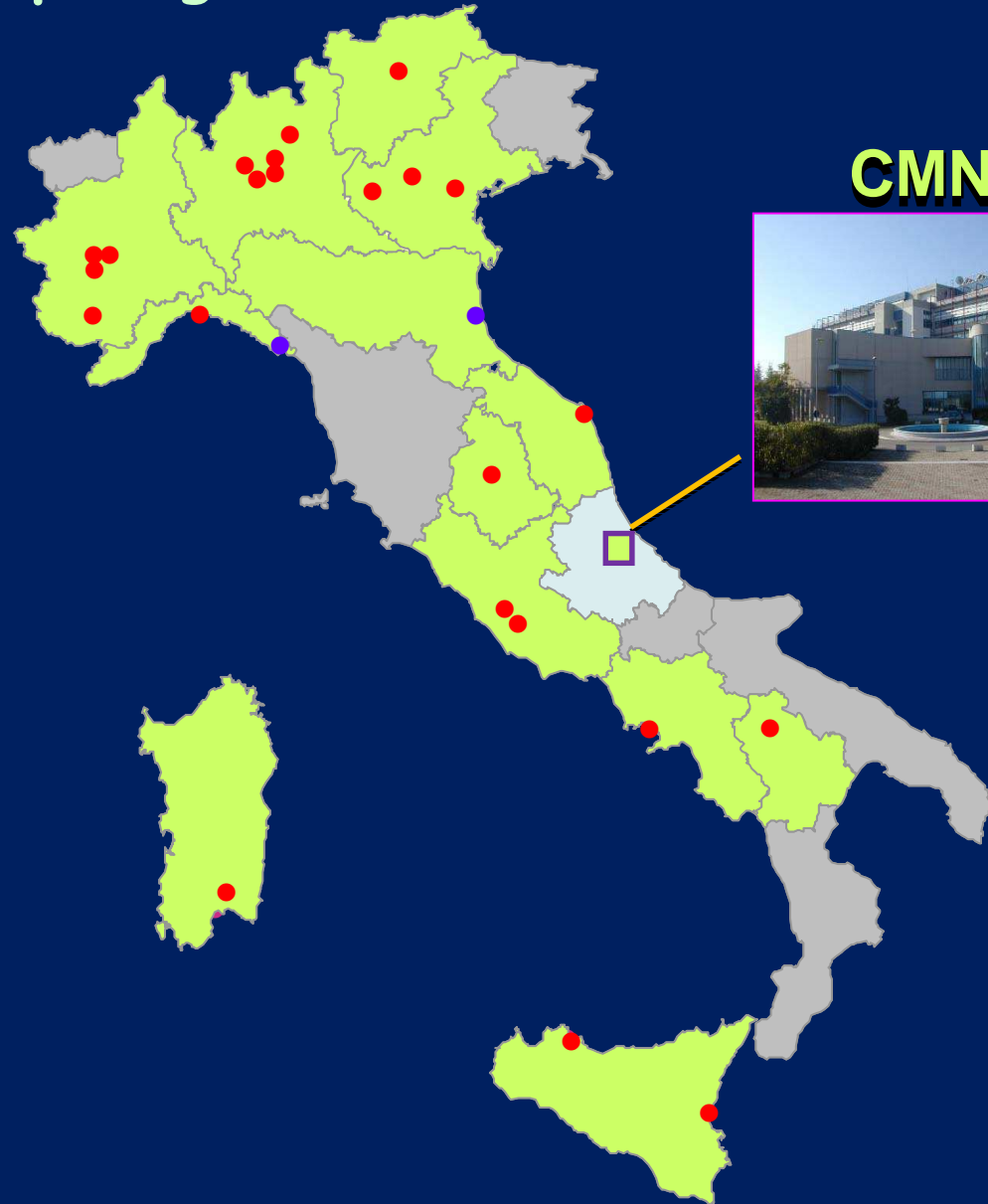


Geographic distribution of participating Centers

NIH registration code:
NCT00795613

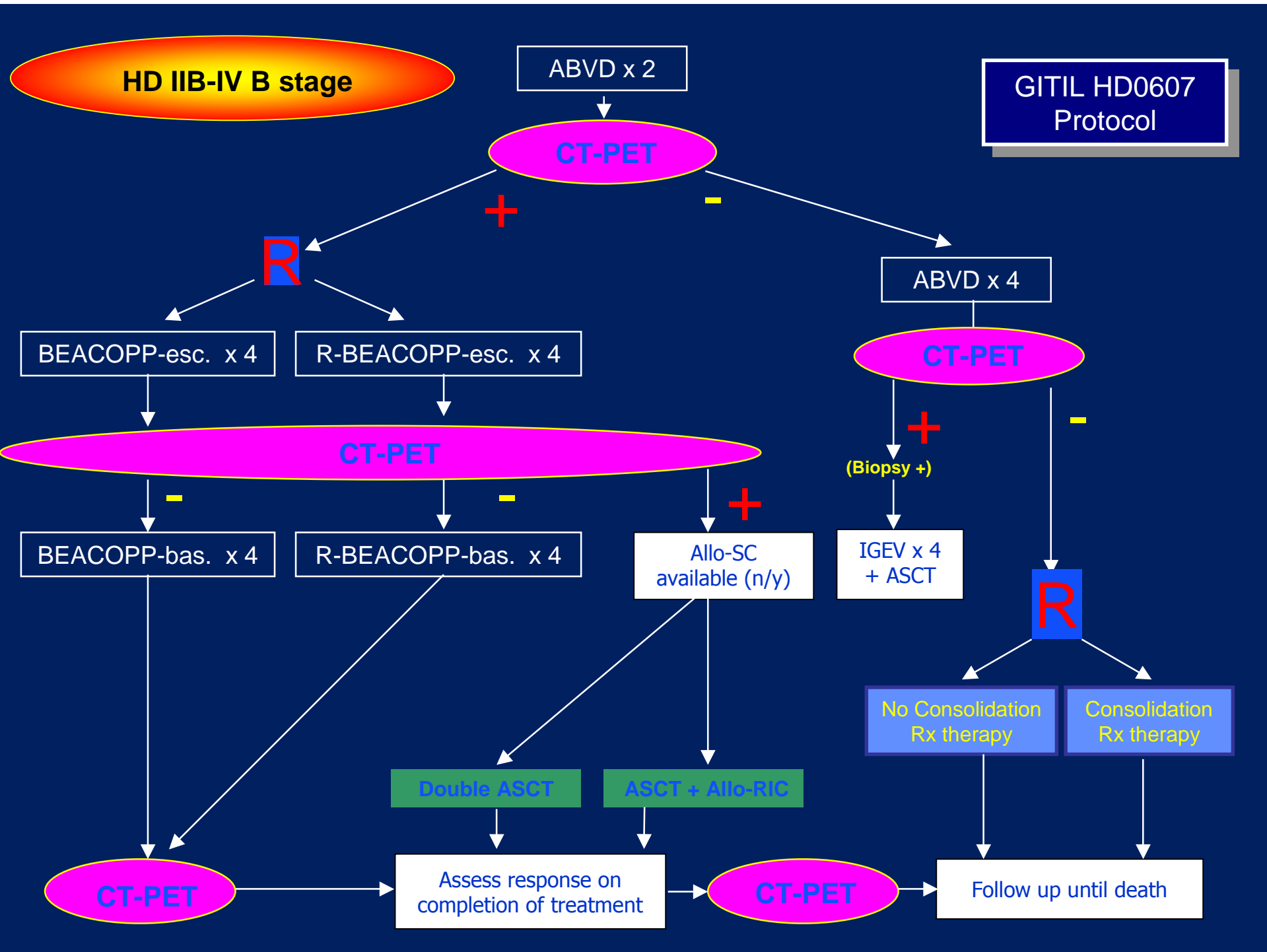
23 centers

- 23 active centers
- 3 center waiting for approval by CE

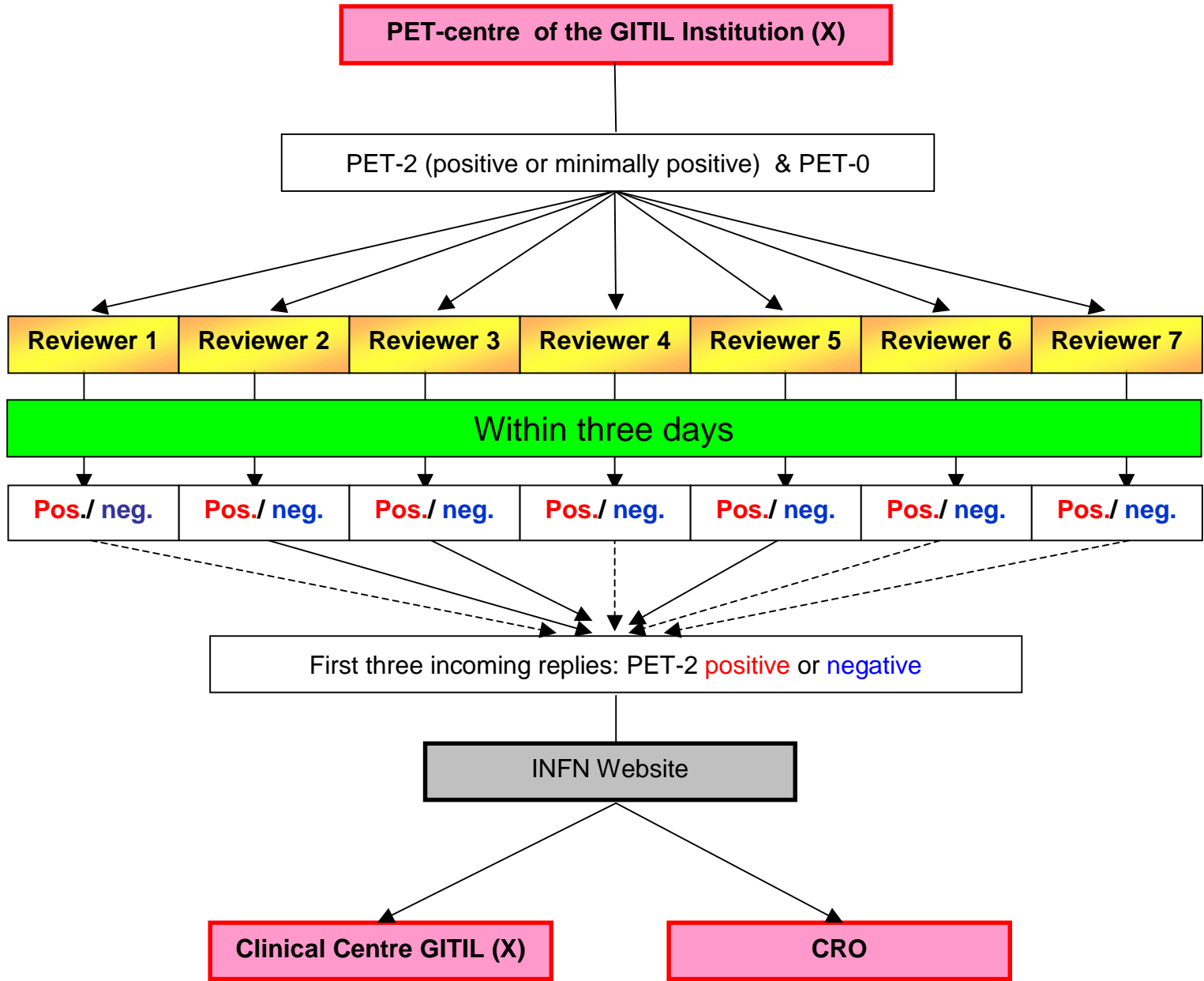


CMNS





Central panel for PET reviewing



PET center uploads PET-0 & PET-2 (positive or minimally positive) on the dedicated WEBSITE of INFN of Turin

PET review panel

E-mail & SMS every 6h

72h First 3 replies

CMNS

Center of scientific and administrative coordination

Clinical Center

RANDOMIZING

<https://heart.negrisud.it/HD/>

GITIL
Gruppo Italiano Terapie Innovative nei Linfomi

Login

Email:

Password:

Login

[Forgot password]

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Protocol GITIL-HD 0607 Login
Databank Server

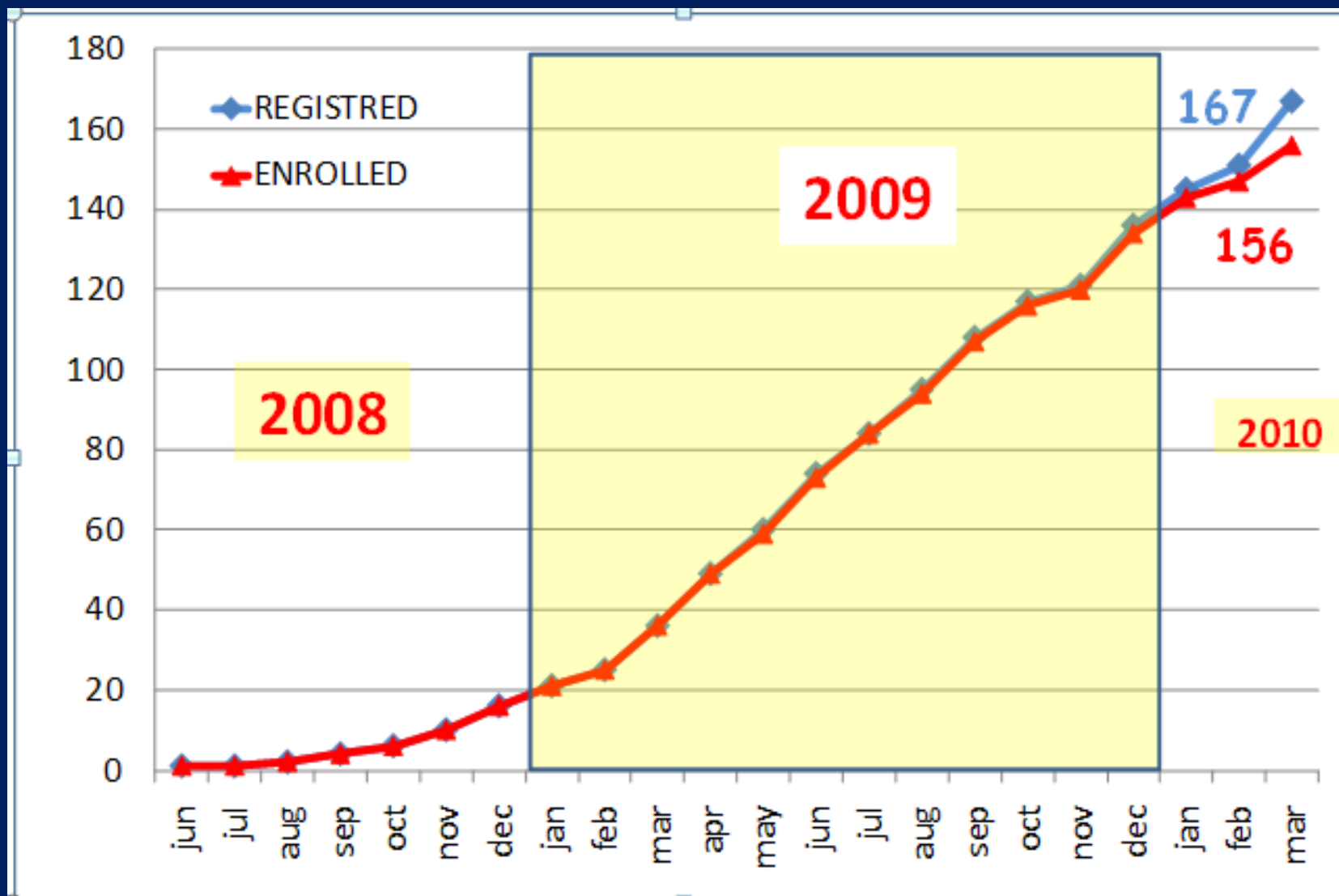
Protocol GITIL-HD 0607

HD 06 07

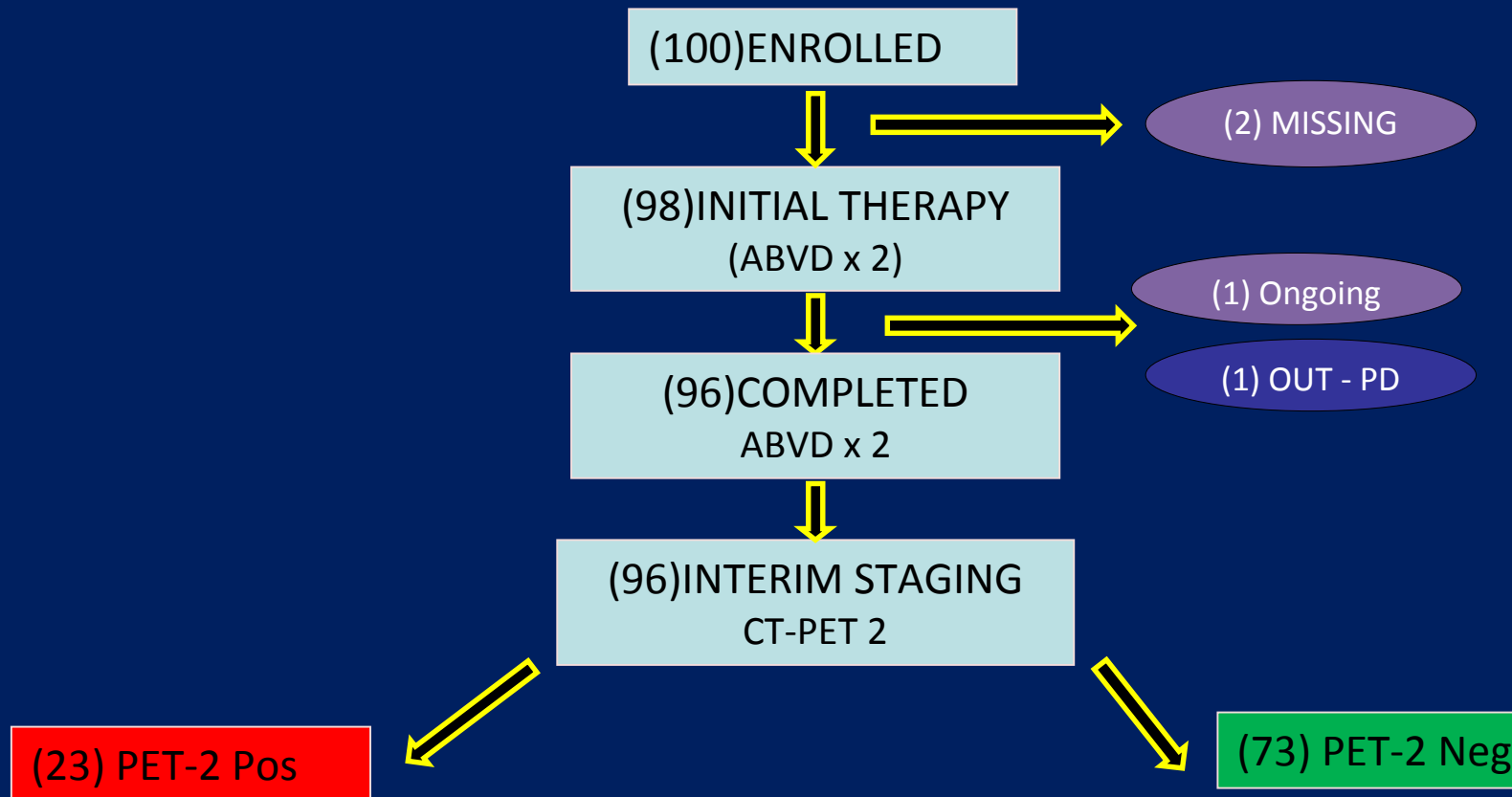
MULTICENTRE CLINICAL STUDY WITH EARLY TREATMENT INTENSIFICATION IN PATIENTS WITH HIGH-RISK HODGKIN LYMPHOMA, IDENTIFIED AS FDG-PET SCAN POSITIVE AFTER TWO CONVENTIONAL ABVD COURSES

Eudract Code: 2007-007168-94

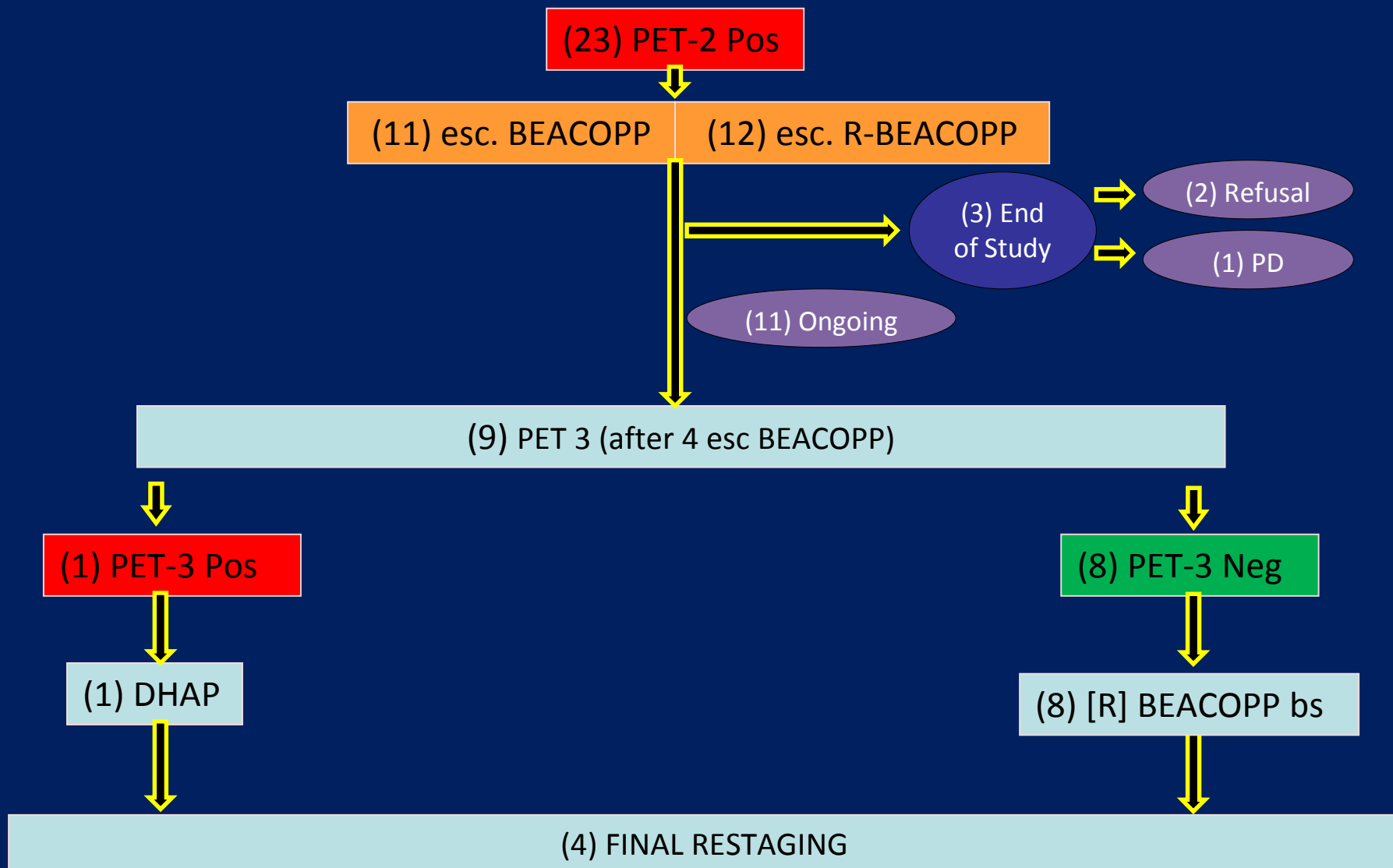
Patient enrolment (30.03.2010)



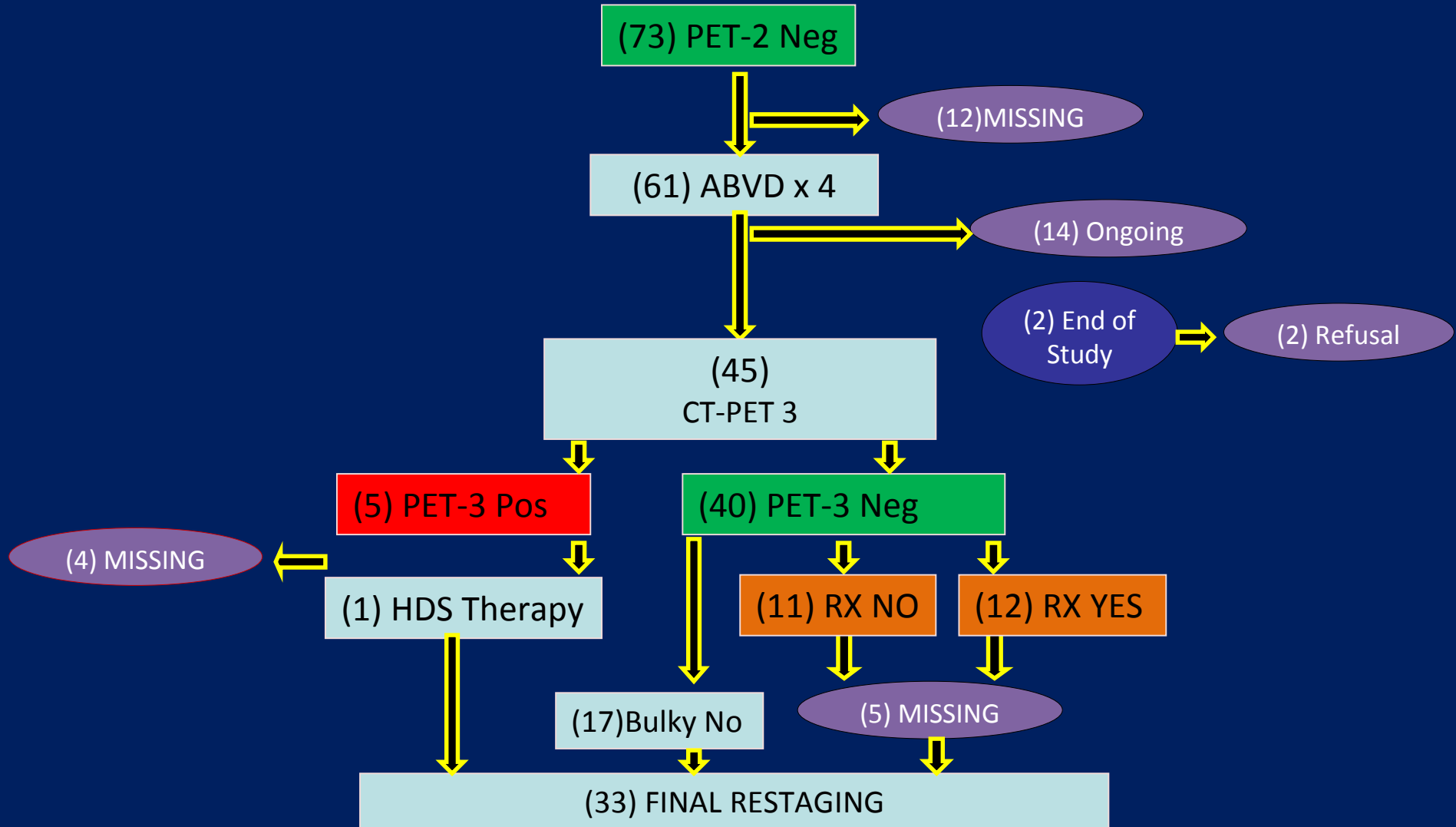
First 100 enrolled patients (30.03.2010)



Interim-PET positive patients (30.03.2010)



Interim-PET negative patients (30.03.2010)



Concordance rate among six reviewers (N=47: 30.03.10)

	Mean	U.F.	F.F.	A.B.	U.G.	F.C	M.G
U.F.	0.66	1	0.84	0.70	0.63	0.53	0.74
F.F.	0.89	0.84	1	0.94	0.66	0.84	0.84
A.B.	0.64	0.70	0.94	1	0.58	0.72	0.88
U.G.	0.51	0.63	0.66	0.58	1	0.63	0.58
F.C.	0.57	0.53	0.84	0.72	0.63	1	0.68
M.G.	0.62	0.74	0.84	0.88	0.58	0.68	1

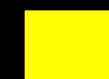
CONCORDANCE



Almost perfect



Substantial



Moderate



k Cohen coefficient

2nd Investigator meeting: Capri, 19.03.2010

