5th International Workshop on PET in Lymphoma
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Ongoing PET oriented trials

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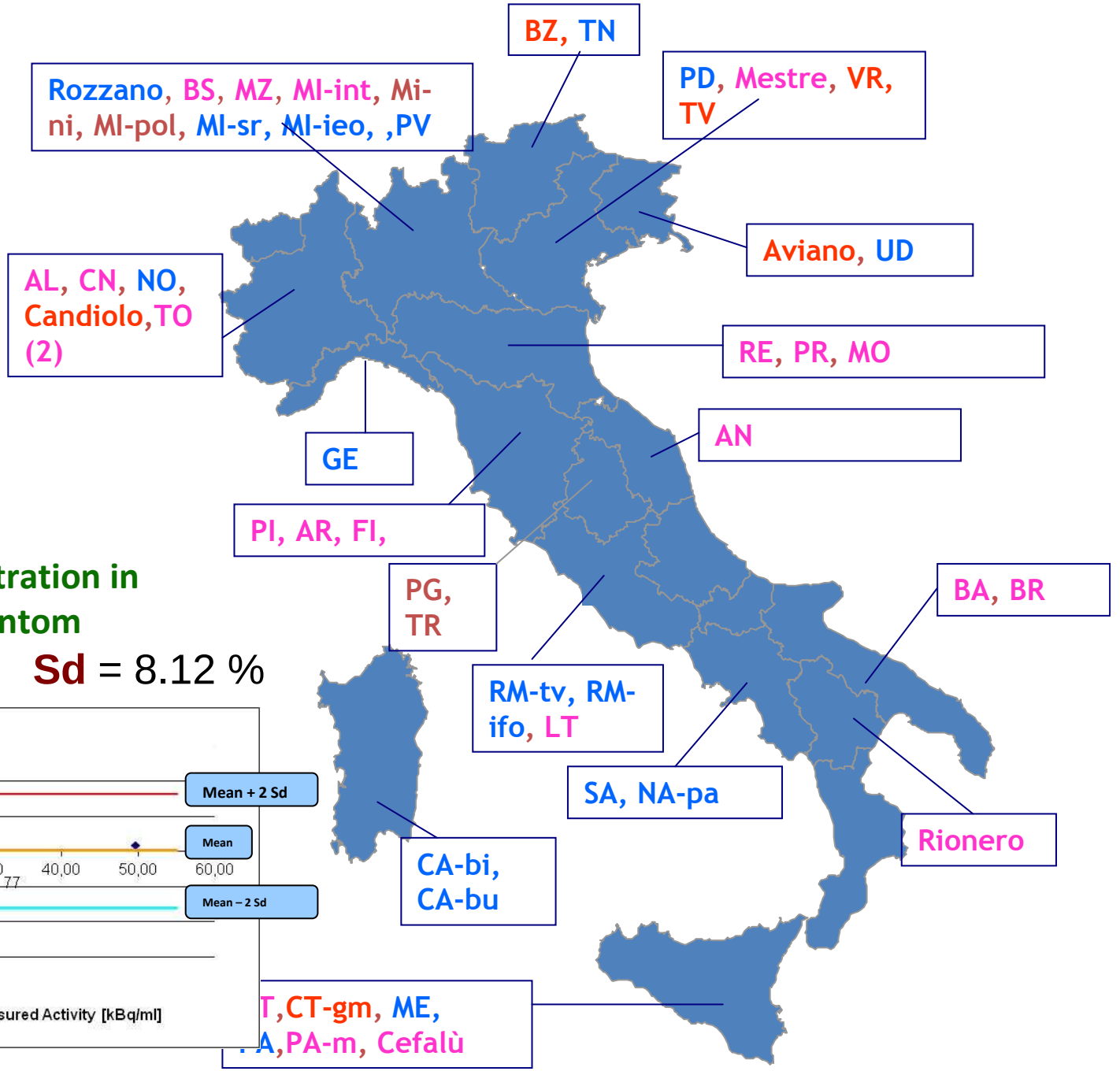
Review process

- Three pillars of reliability of PET data:
  - Central panel review:
    - Deauville criteria with 5 point-scale
    - WIDEN for image exchange
  - PET procedure harmonization:
    - common protocol valid for all FIL sponsored studies
    - real time analysis of violation with WIDEN
  - PET scanner equalization in Cuneo Core Lab
    - 22 oncological trials, 168 PET sites in 19 countries

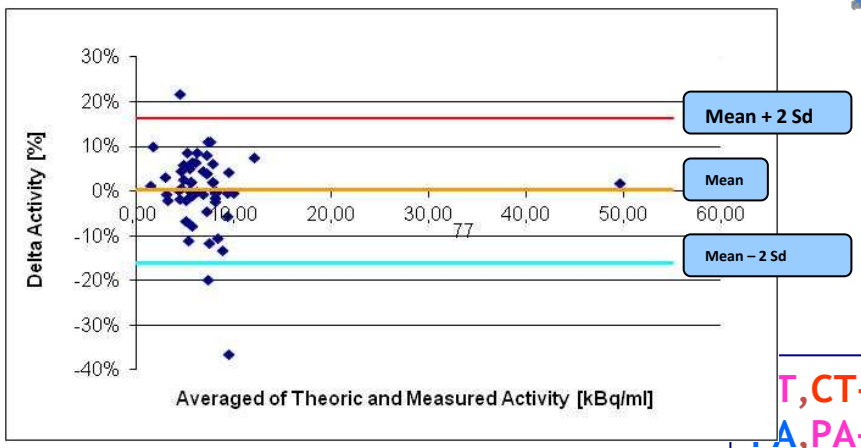
Cuneo Core Lab

49 PET Sites



Activity concentration in uniform phantom

Mean = 0.16 % **Sd** = 8.12 %



Ongoing PET-based clinical trials from FIL

Disease	Stage	Patients N°	Trial	Site	Central review	PET adapted	status
HL	I-IIA	86/86	dd-ABVD	Italy	Yes	No	Open
HL	I-IIA	19/130	2P-PET	Italy	Yes	No	Open
HL	Rel/ref	0/13	BRIDGE	Italy	Yes	Yes	Open
DLBCL	II-IV	36/110	DLCL-10	Italy	Yes	Yes	Open
PMBCL	I-II	120*/752	IELSG-37	World	Yes	Yes	Open
FL	II-IV	208/600	FOLL 12	Italy	Yes	Yes	Open
	Tot.	469/1691					

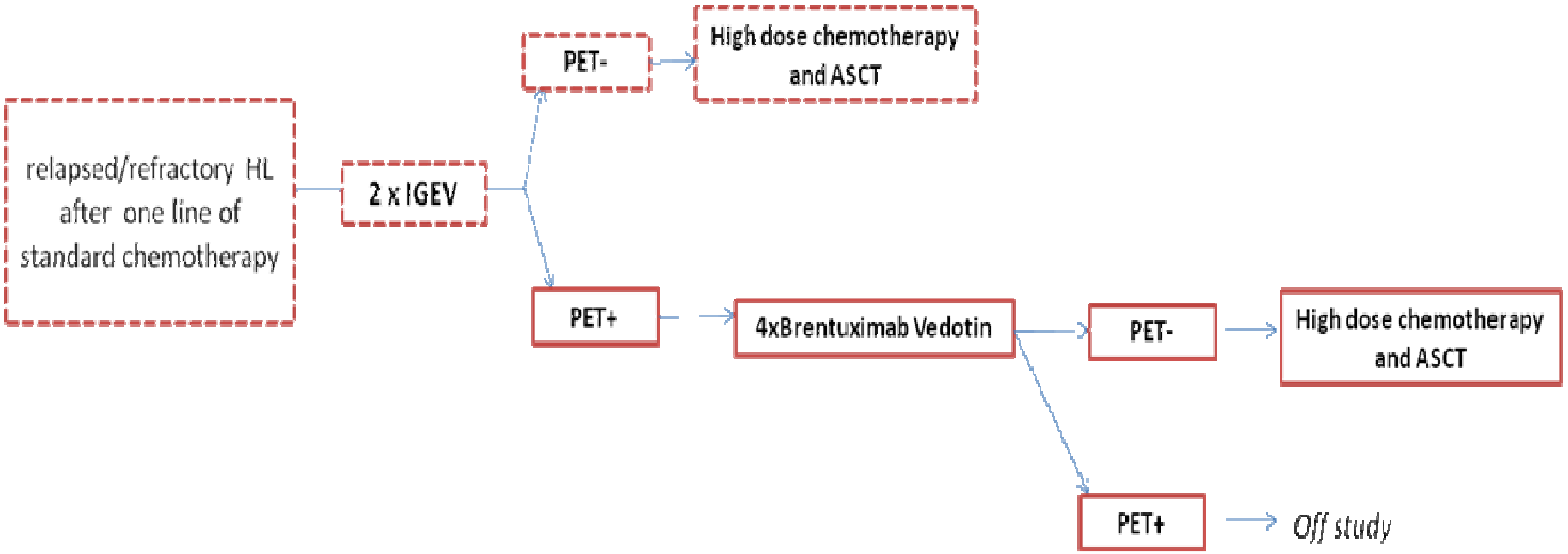
FIL repository of PET images (B,I,F) (also including closed studies studies)

- HL 865/957 (6 studies)
-NHL:
  - DLBCL 156/872 (2 studies)
  - FL 332/724 (2 studies)

* 86 cases from FIL centers

BRidge

A pilot phase II study with BRENTUXIMAB VEDOTIN as pre-ASCT induction therapy in relapsed/refractory Hodgkin's lymphoma patients not responding to IGEV salvage treatment



Study coordinators: A.M. Carella, M. Federico

OBJECTIVES

Primary objective

To evaluate the activity of brentuximab vedotin in terms of complete remission (CT scan and FDG-PET negative) in patients with relapsed/refractory HL not responding (FDG-PET positive) to salvage treatment with IGEV.

Secondary objectives

To evaluate if brentuximab vedotin administration after unsatisfactory response to IGEV is able to achieve CR, thus improving PFS and duration of remission.

To evaluate the toxicity of brentuximab vedotin in terms of haematological and extra-haematological side effects.

Accrual and study duration

SAMPLE SIZE : **13 patients (8 Centers)**

Study duration : **2 years and a half**

12 months to complete accrual + 12 months of follow-up (from the date the last patient starts treatment)

Study start: **October 2014**

(only Coordinating Center active at present)

DLCL10

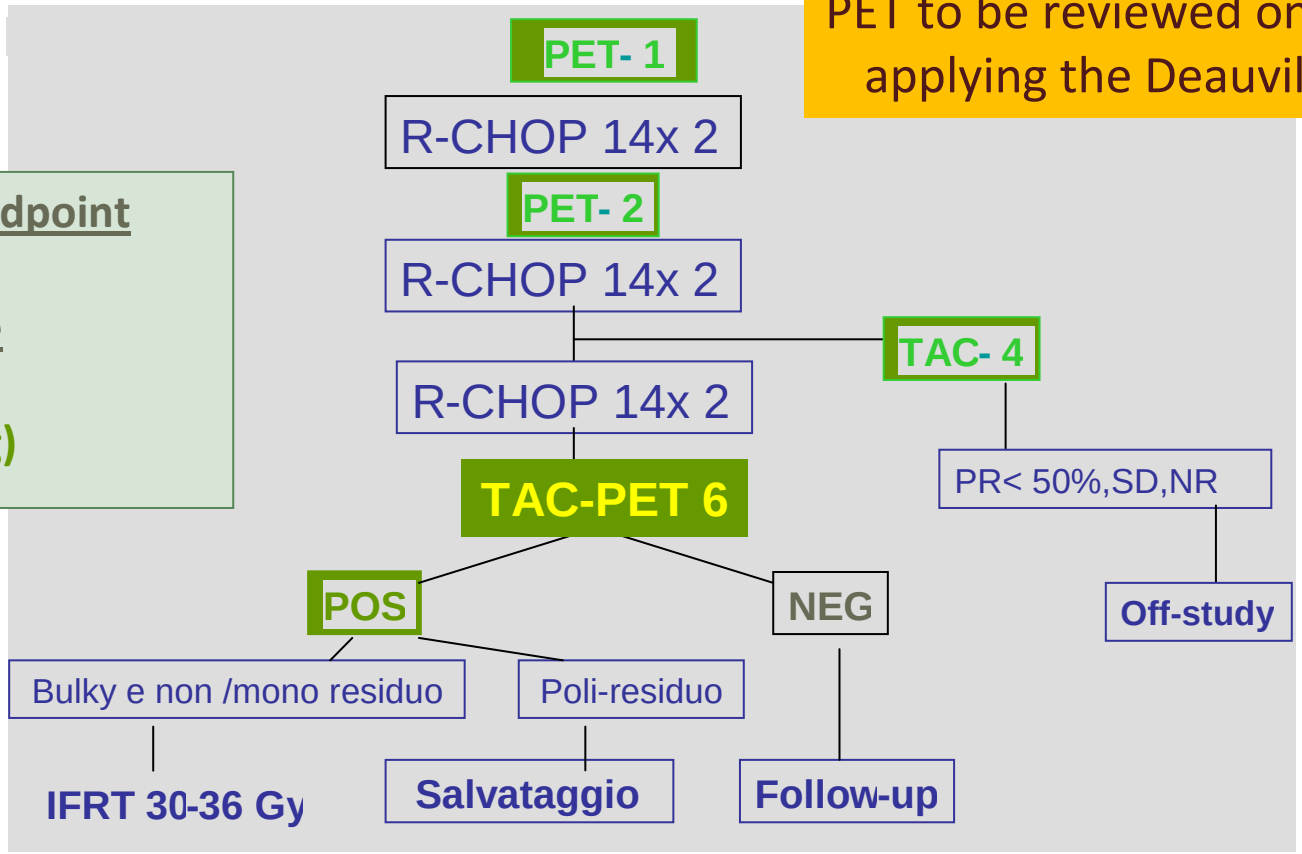
Prospective, multicentre phase II study with R-CHOP- 14 & consolidation PET–oriented radiotherapy in DLBCL patients with low risk profile according to age-adjusted IPI (0 with bulky or 1)

- DLBCL, FL grade IIIB, DLBCL T-cell rich
- 18-70 aa
- aaIPI=1 +/- bulky
- aaIPI=0 + bulky (> 7,5 cm)

PET to be reviewed on WIDEN applying the Deauville 5PS

Primary endpoint
2-yrs PFS

Sample size
112 pts
(67 PET neg)



PI: MG Cabras , M Balzarotti - Coordinating Center : Cagliari

DLCL 10 – status on 31/08/2014

Authorized sites	22
Active sites (at least one patient entered)	11
Planned accrual	112
Current accrual	34
1° patient entered	02/01/2012

Pts registered	PET submitted for review	PET evaluated by reviewers so far	PET negative (5PS 1-2)	PET positive (5PS 3-5)
34	26	21	17	4

A randomized, open-label, multicentre, two-arm phase III comparative study assessing the role of involved mediastinal radiotherapy in Primary Mediastinal Large B-Cell Lymphoma (PMLBCL) – IELSG37

Clinical Trial coordinators

M. Martelli – Roma (Italy)
M.Gospodarowicz Toronto (Canada)
A.J Davis - Southampton (UK)
E. Zucca - Bellinzona (Switzerland)

PET Trial coordinators

S.Barrington London (UK)
A.Biggi Cuneo (Italy)
L. Ceriani Bellinzona (Switzerland)
A. Versari - Reggio Emilia (Italy)

Study design

Diagnosis PMLBCL
Registration

PET-CT 0

* R-CHOP 14/21; R-V/MACOP-B
R-DAEPOCH; R-ACVBP; R Mega-CHOP

Standard therapy

* R-Chemo

PET-CT 1 (5-6week)
Central review

Positive

Negative

Randomized 1:1

Treatment based on investigator choice
(follow-up for PFS)

IFRT

Observation

IELSG37

- IELSG-FIL collaboration
- Italian clinical trial coordinator: M. Martelli (Roma)
- Started from **May 2012**
- Expected end time: **5** years from last patient randomization
- Expected accrual: **376** with PET- after R-CHT (**752** total patients)
- Current accrual: **120** patients (**86** from FIL)

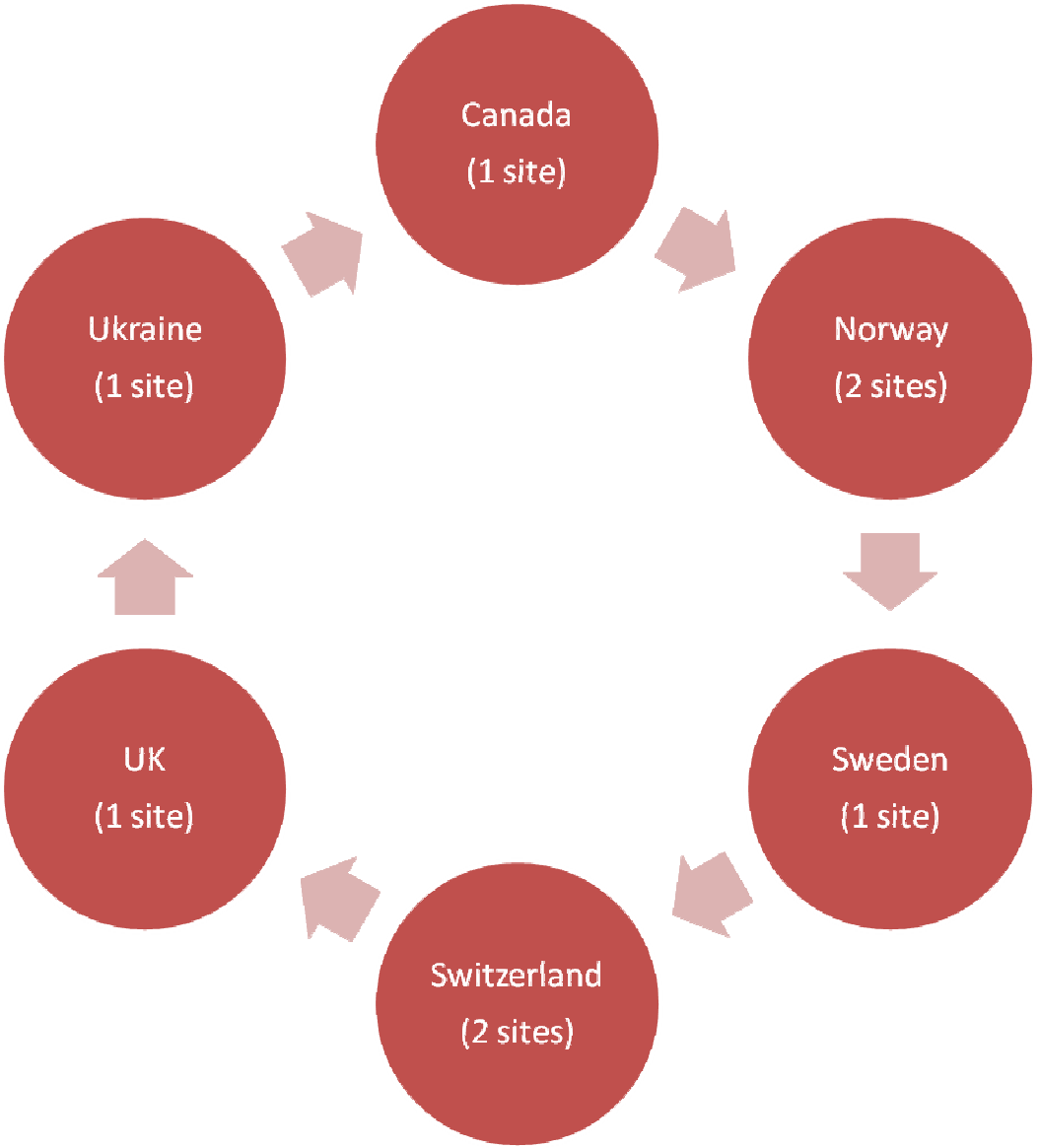
IELSG37: Italian sites

58	• Participating sites
42	• Active sites
25	• Recruiting sites

IELSG37: Foreign sites

25	• Active sites
8	• Recruiting sites

IELSG37: foreign recruting sites



Central PET Review After Chemoterapy (September, 15 2014)

PET POSITIVE	PET NEGATIVE	PET REVIEWED
59	33	92

Randomization Results (September 10, 2014)

ARM A (RADIOTHERAPY)	ARM B (OBSERVATION)	RANDOMIZED PATIENTS
17	16	33

FOLL12

A multicenter, phase III, randomized study to evaluate the efficacy of a response-adapted strategy to define maintenance after standard chemoimmunotherapy in patients with advanced-stage Follicular Lymphoma

EUDRACT NUMBER 2012-003170-60

STUDY COORDINATORS ***Maura Brugiatelli***
Massimo Federico

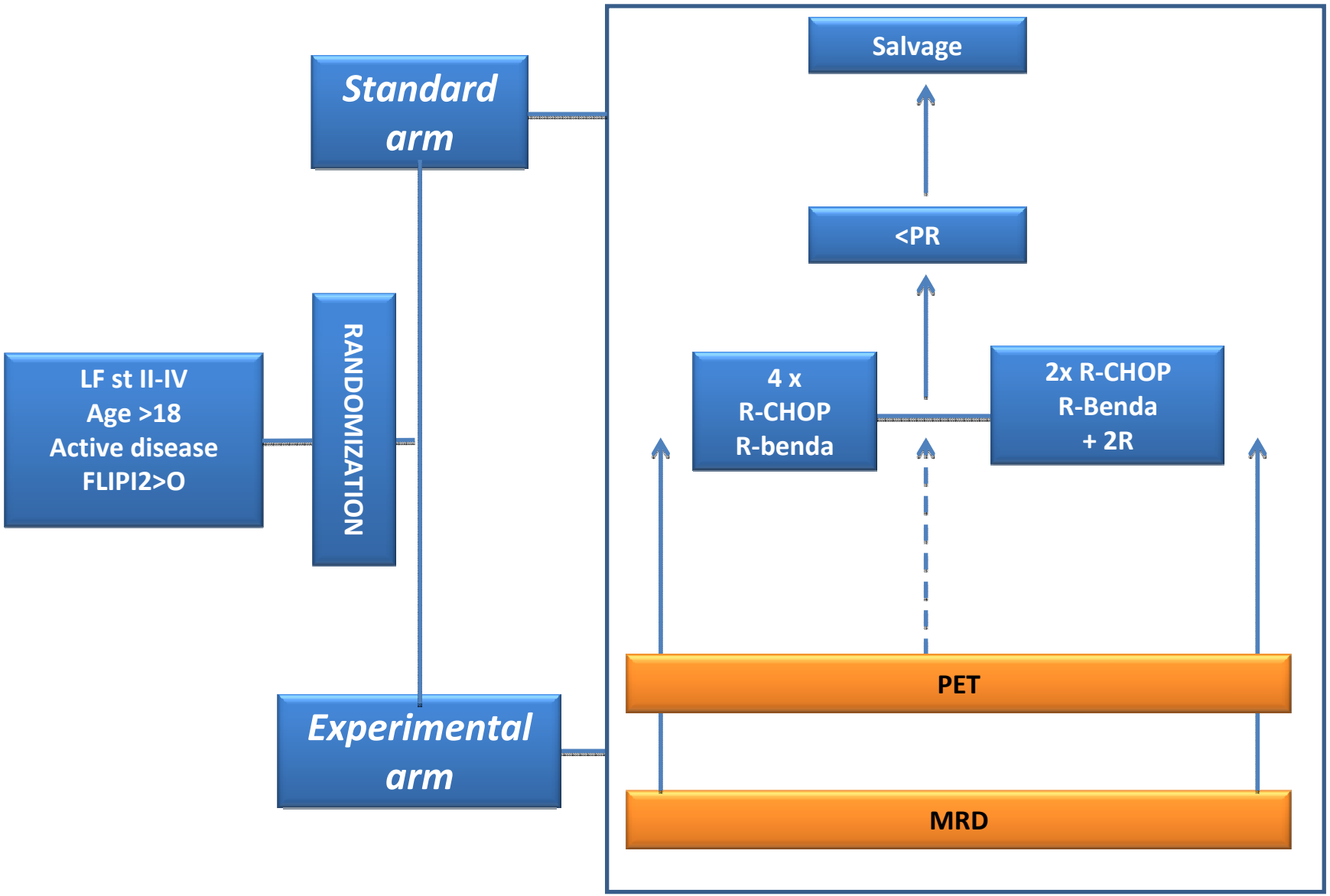
OBJECTIVES

Primary objective

Evaluate whether a **PET** and **MRD response-based maintenance** therapy is more effective in terms of **PFS** than a **standard maintenance** therapy with R in patients with untreated, advanced FL

TRIAL DESIGN

Induction therapy



TRIAL DESIGN

Maintenance