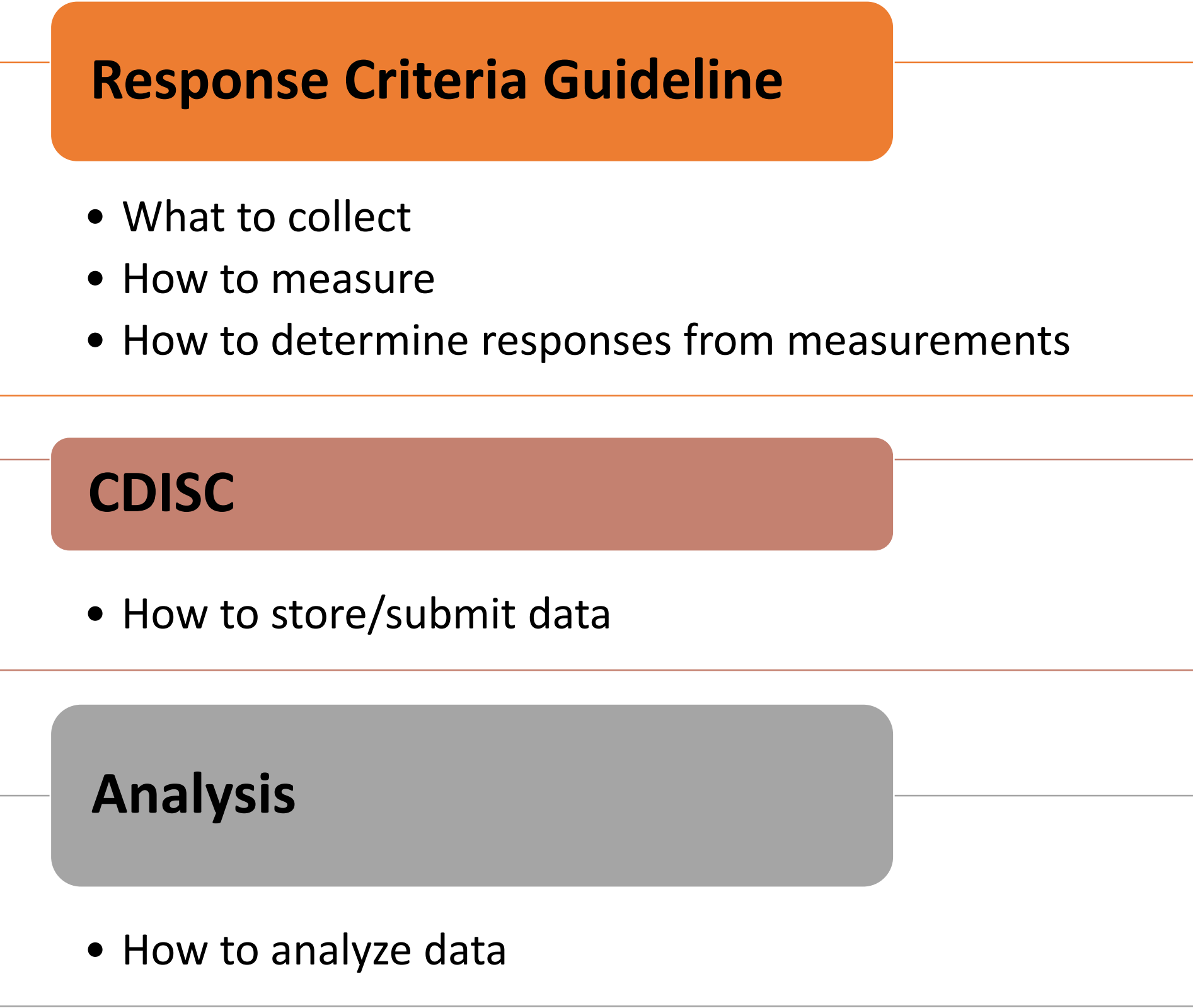


End to End Standards driven Process for Oncology Studies

Kevin Lee at klee@clindatainsight.com, Peng Yang at pyang@clindatainsight.com

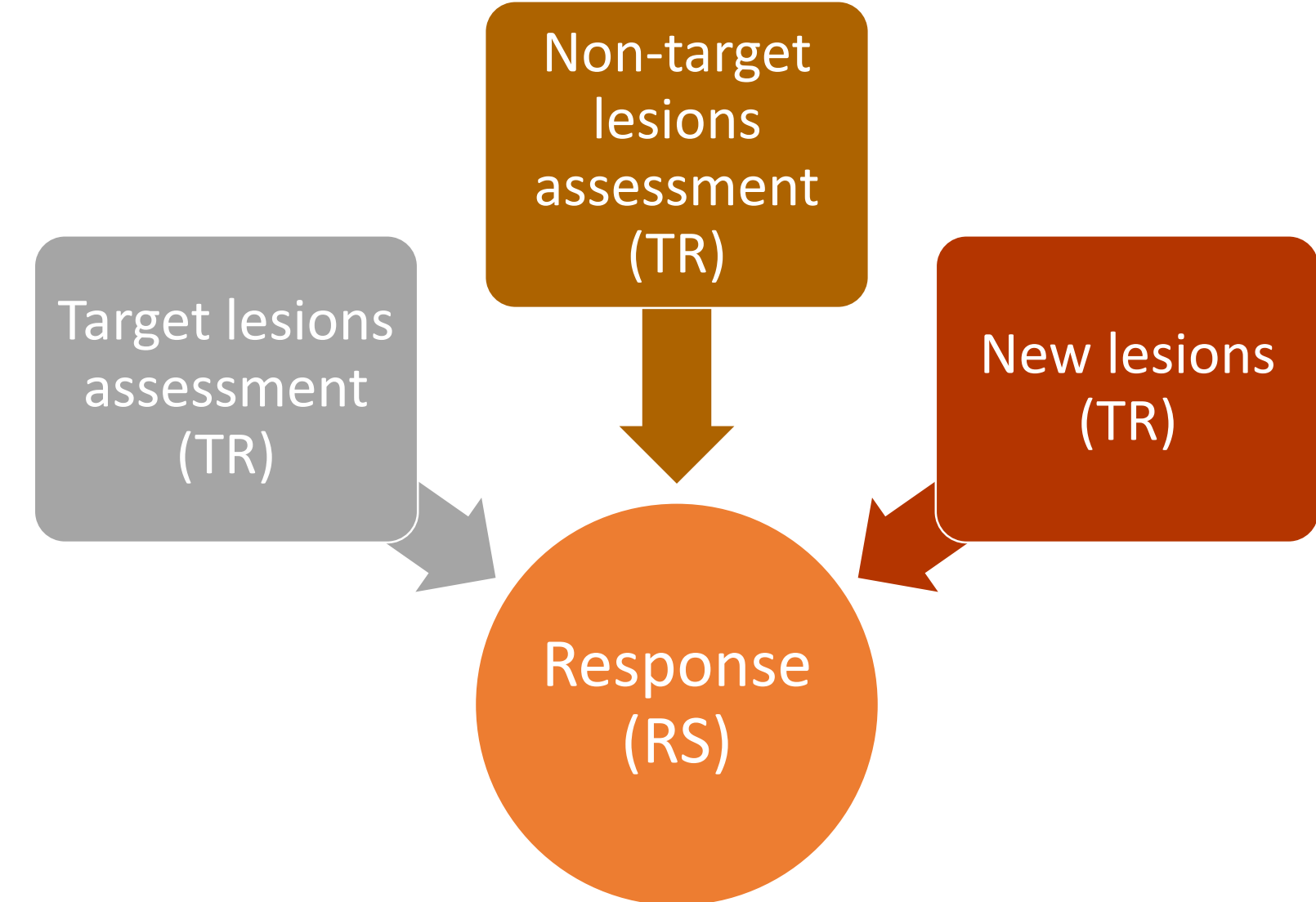
Oncology Studies specific Components



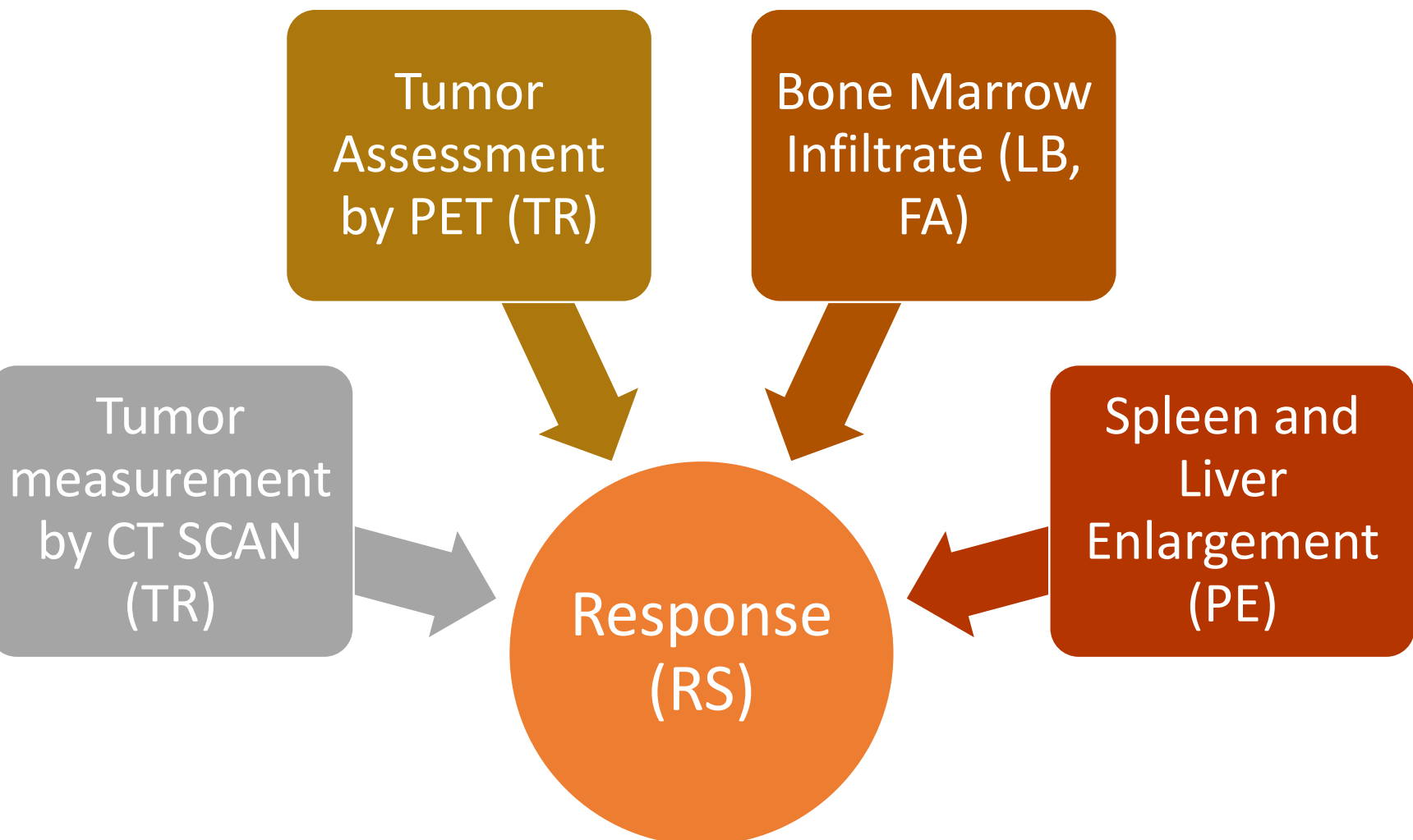
Oncology Study types driven Response Criteria

Solid Tumor	Lymphoma	Leukemia
<ul style="list-style-type: none">RECIST (Response Evaluation Criteria in Solid Tumor) 1.1irRC(Immun e-related RECIST) 2009	<ul style="list-style-type: none">Cheson 2007Cheson 2014	<ul style="list-style-type: none">IWCLL 2008IWAML 2003NCCN Guideline 2012 on ALLCML ESMO Guidelines

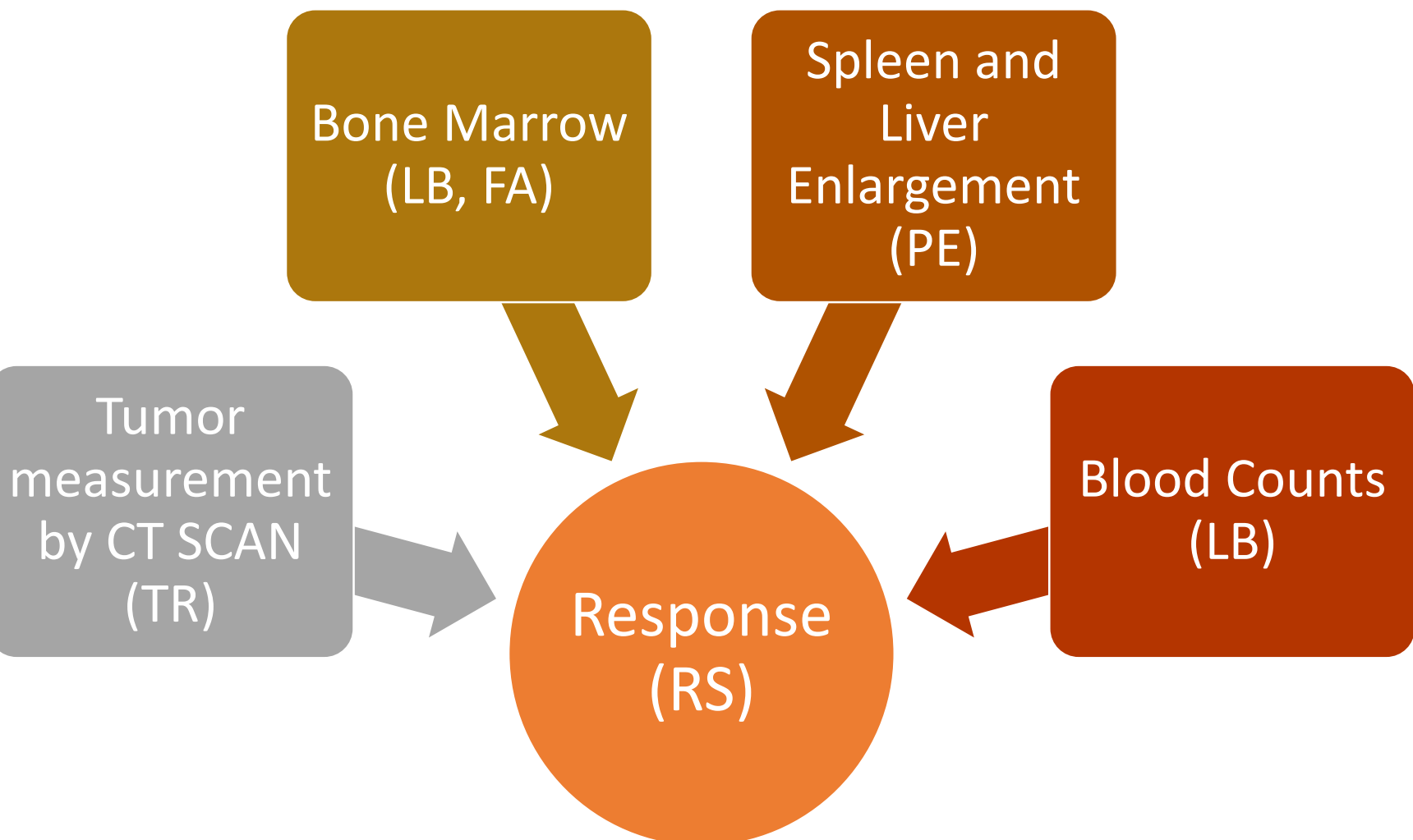
RECIST 1.1 driven Data Collection and SDTM



Cheson 2014 driven Data Collection and SDTM



IWCLL 2008 driven Data Collection and SDTM



Oncology specific SDTM TR domain

USUBJID	TRLI NKID	TRTEST	TRCAT	TROR RES	TROR RESU	VISIT
001-01-001	T01	Longest Diameter	Measure ment	23	mm	Screening
001-01-001	T02	Longest Diameter	Measure ment	22	mm	Screening
001-01-001	T03	Longest Diameter	Measure ment	25	mm	Screening
001-01-001		Sum of Diameter	Measure ment	70	mm	Screening

Oncology specific SDTM RS domain

USUBJID	RSTESTCD	RSTEST	RSCAT	RSORRES	VISIT
001-01-001	TRGRESP	Target Response	RECIST 1.1	PR	Visit 1
001-01-001	NTRGRESP	Non-target Response	RECIST 1.1	NonCR/NonPD	Visit 1
001-01-001	NEWLPROG	New Lesion Progression	RECIST 1.1	Y	Visit 1
001-01-001	OVRLRESP	Overall Response	RECIST 1.1	PD	Visit 1
.....					
001-01-001	BESTRESP	Best Response	RECIST 1.1	PD	

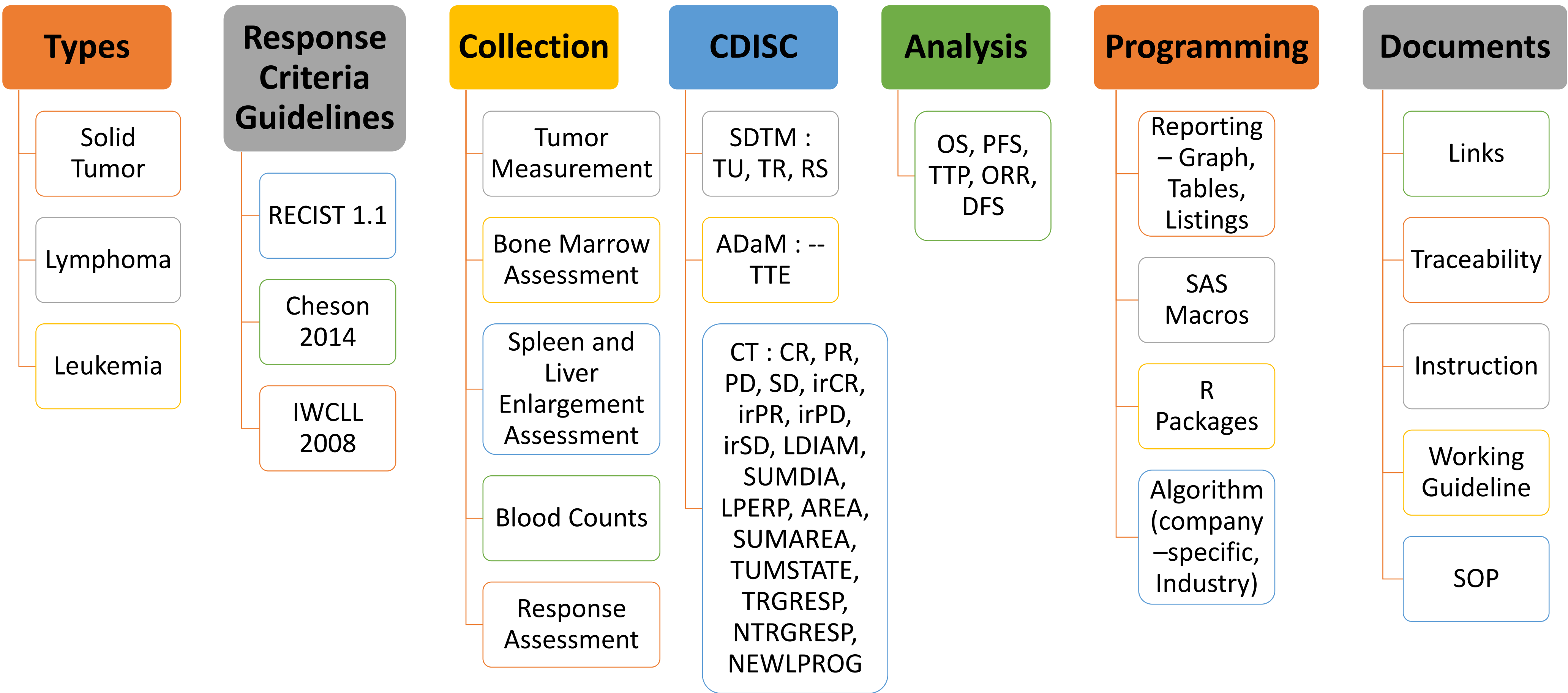
Oncology specific Time to Event ADaM dataset for PFS

USUBJID	TRTP	PARAM	AVAL	STARTD T	ADT	CN SR	EVNTDESC
001-01-001	Study Drug 1	Progression Free Survival (Days)	157	2011-01-04	2011-06-10	0	PROGRESSIO N DISEASE
001-01-002	Study Drug 2	Progression Free Survival (Days)	116	2011-02-01	2011-05-28	1	LOST TO FOLLOW-UP
001-01-003	Study Drug 2	Progression Free Survival (Days)	88	2011-02-05	2011-05-04	0	DEATH
001-01-004	Study Drug 1	Progression Free Survival (Days)	102	2011-03-20	2011-06-30	1	COMPLETED THE STUDY
001-01-005	Study Drug 1	Progression Free Survival (Days)	101	2011-03-26	2011-07-05	1	ONGOING

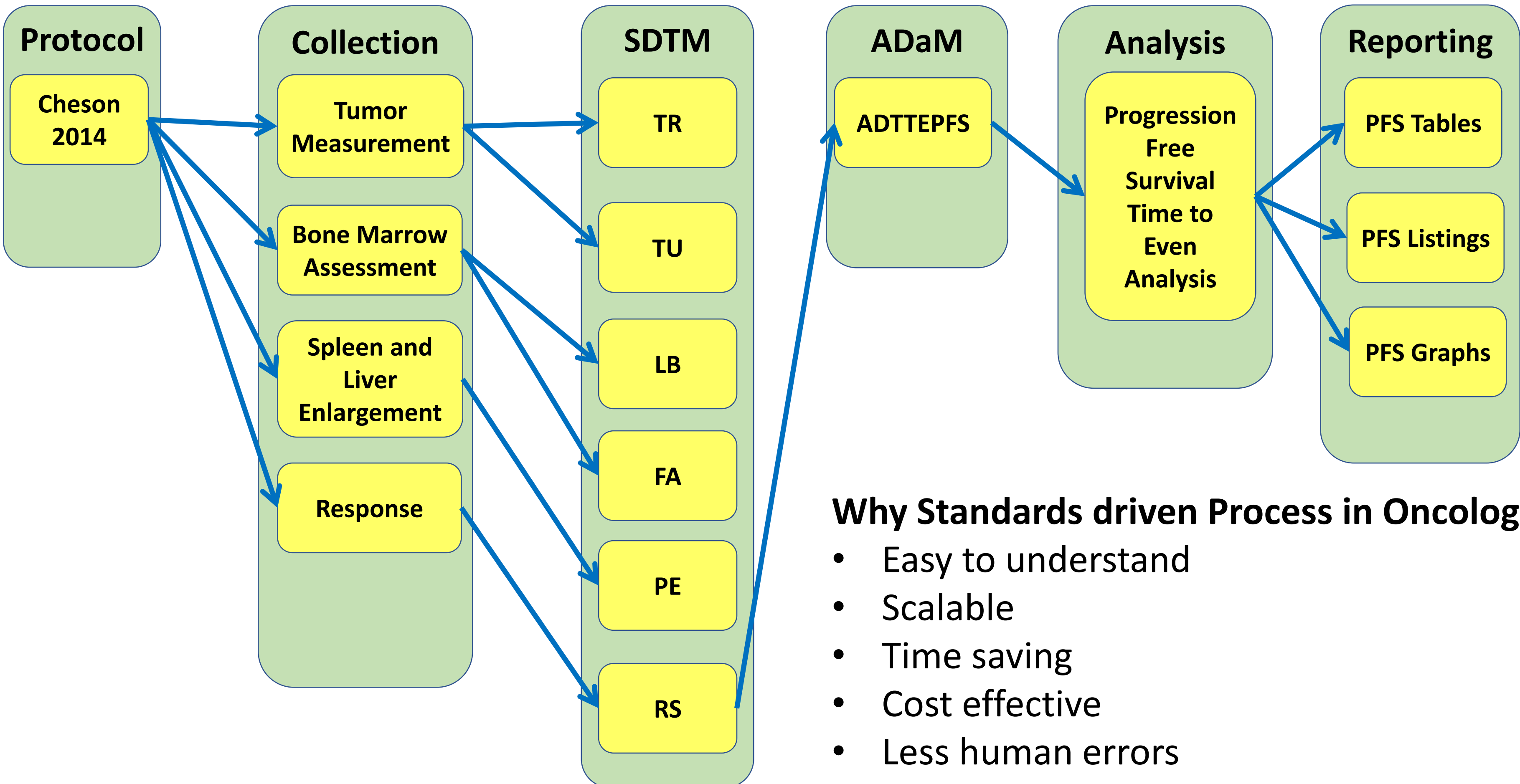
Oncology specific PFS Analysis

PROC LIFETEST data=**ADTTEPFS**;
WHERE PARAMCD = "PFS";
TIME AVAL*CNSR(1);
STRATA TRTP;
RUN;

Oncology-specific Standards



Case Study: End to End Standards-driven Process for Lymphoma Study



Why Standards driven Process in Oncology Studies

- Easy to understand
- Scalable
- Time saving
- Cost effective
- Less human errors