



“The important thing is not to stop questioning. Curiosity has its own reason for existing.” - Albert Einstein

ZIFO

RnD SOLUTIONS

Drug Discovery | Clinical Development | Manufacturing QC | Genomics

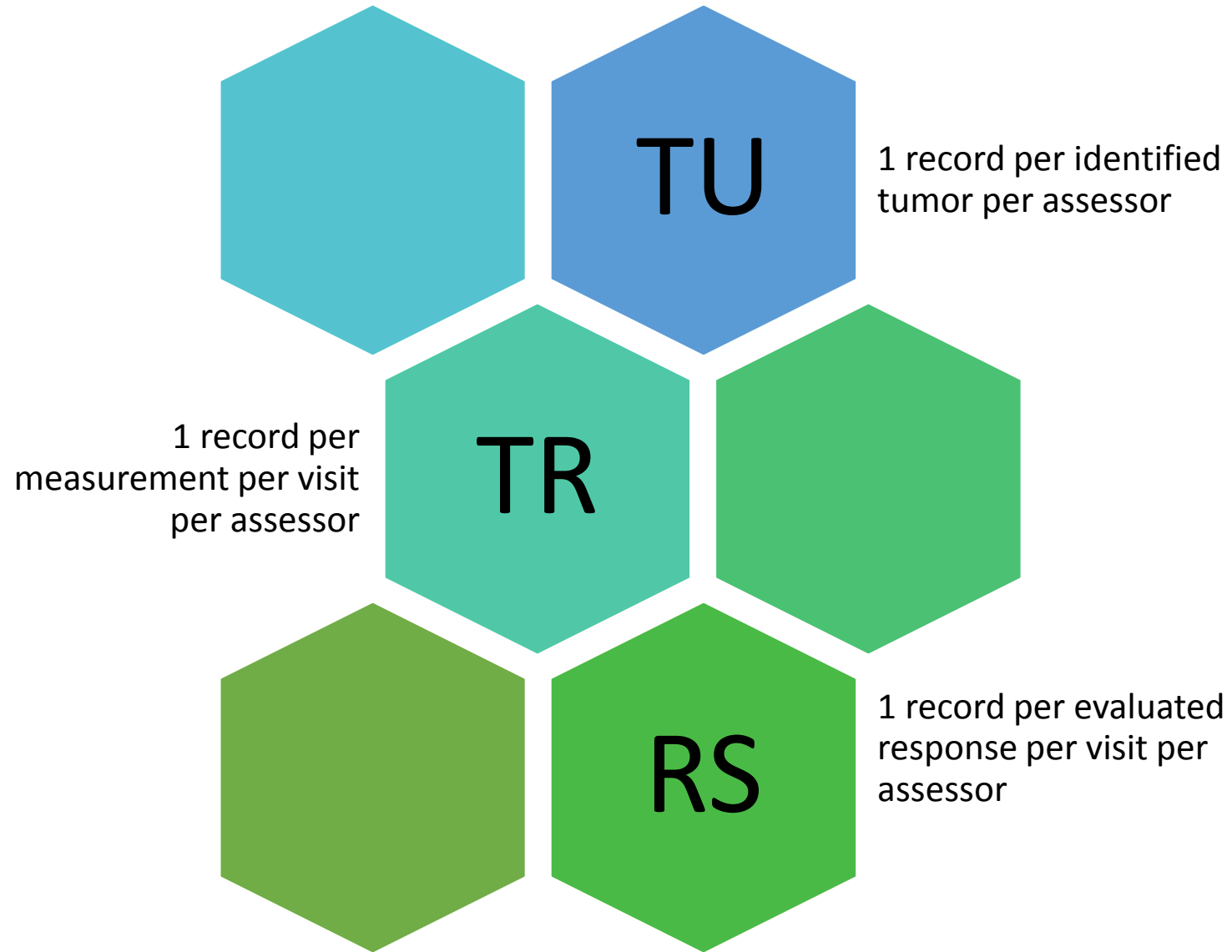
R&D IT | Clinical Biometrics | Compliance Solutions | Scientific Process Management

From Data to Decisions
Things You Never Want to Miss in Oncology
Data

Track the Tumor!

Understanding Tumor identification and Categorization

Ensure the identified tumors retains its type throughout the study



CRF data

Sub	Visit	Lesion no.	Tumor Identification	Longest Diameter
001	Screening	1	By-stander	10
001	Cycle 1 Day 1	1	By-stander	12
001	Cycle 2 Day 1	1	Target	12

TU domain

USUBJID	TUGRPID	TULNKID	TUTESTCD	TUORRES	VISIT
STUDY-001	01	BY-01	TUMIDENT	By-stander	Screening
STUDY-001	01	T-01	TUMIDENT	Target	Cycle 2 Day 1

TR domain

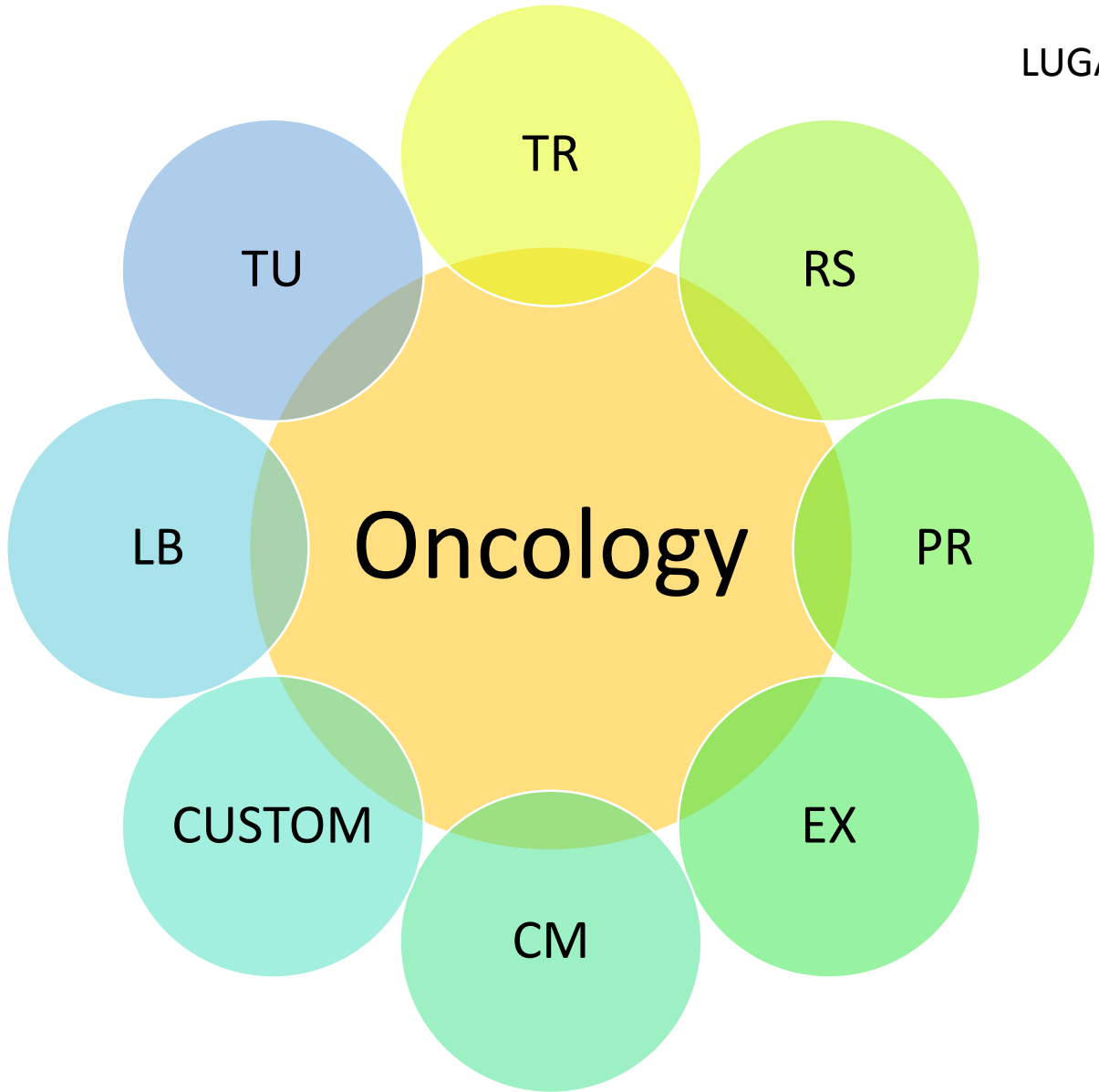
USUBJID	TRLNKID	TRTESTCD	TORRES	VISIT
STUDY-001	BY-01	LDIAM	10	Screening
STUDY-001	BY-01	LDIAM	12	Cycle 1 Day 1
STUDY-001	T-01	LDIAM	12	Cycle 2 Day 1

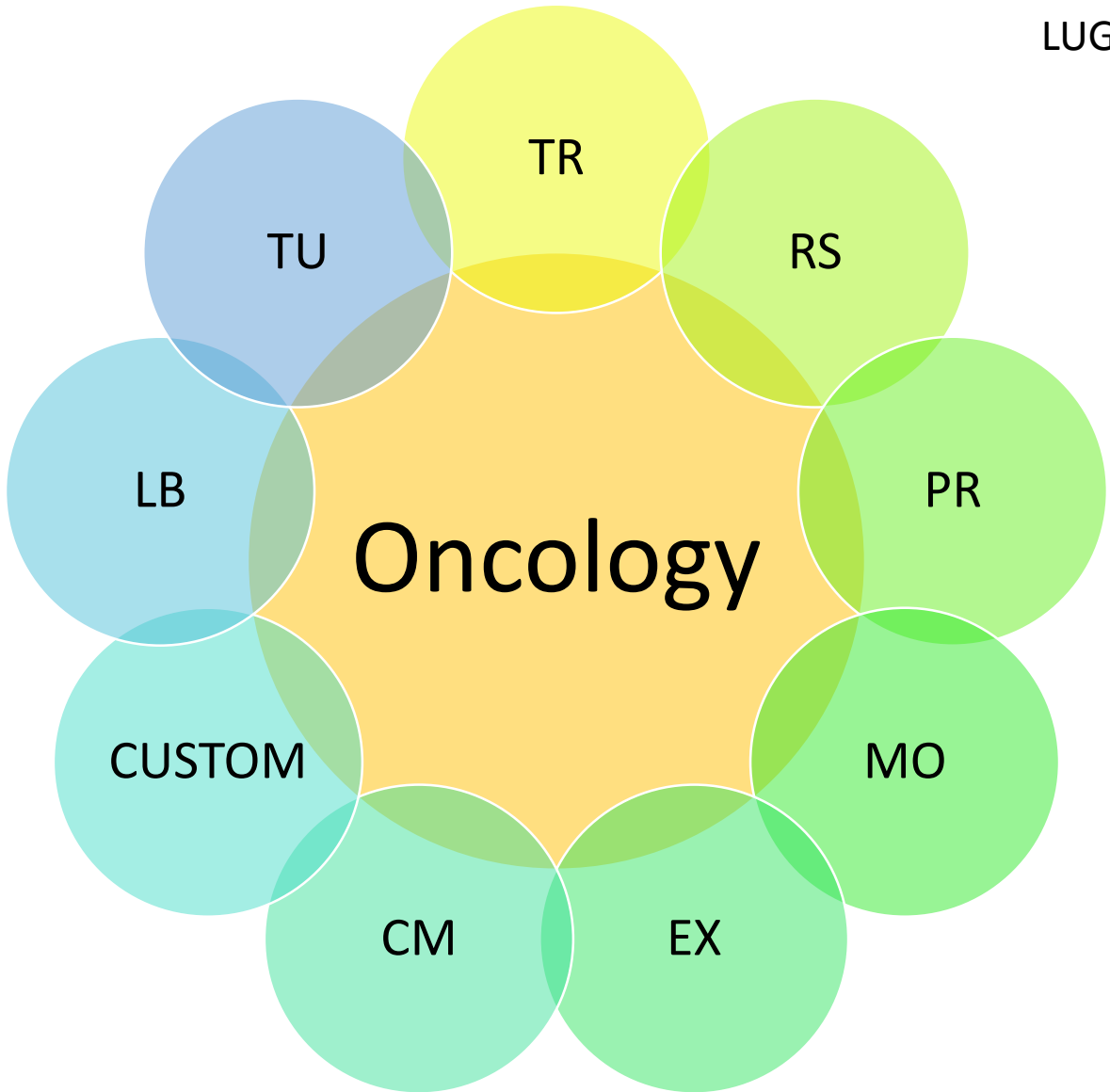
More to the Package!

Data goes into various domains

Effective linking

Effective use of available variables





LNKID

- TU - TR
- Required in RS when other linking variables cannot uniquely link to data in another domain

LNKGRP

- TR - RS : When results are used to evaluate response

GRPID

- TU : Tumor split or merge
- RS : More than 1 type / source of assessments related to collected response

REFID

- Identification data such as test for lesion confirmation or sample collection is available from other domain

MO domain

USUBJID	MOLNKID	MOTEST	MOORRES
STUDY-001	001-Cycle 1	Liver Abnormal Vertical Length	11
STUDY-001	001- Cycle 3	Liver Abnormal Vertical Length	7

TR domain

USUBJID	TRLNKGRP	TRTEST	TRORES
STUDY-001	001-T-01-Cycle 1	Longest Diameter	7.5
STUDY-001	001-T-01- Cycle 3	Longest Diameter	5

RS domain

USUBJID	RSLNKID	RSLNKGRP	RSTEST	RSORRES
STUDY-001	001-Cycle 1	001-T-01-Cycle 1	Overall Response	SD
STUDY-001	001- Cycle 3	001-T-01- Cycle 3	Overall Response	PR

When is the last appointment?

Handling indefinite visits

Visits depend on the progress of subject
in the study

TV domain

STUDYID	VISIT	VISITNUM
STUDY	SCREENING	1
STUDY	CYCLE 1 DAY 1	2
STUDY	CYCLE 2 DAY 1	3
STUDY	.	.
STUDY	.	.
STUDY	.	.
STUDY	CYCLE x DAY 1	x+1
STUDY	FOLLOW-UP 1	101
STUDY	FOLLOW-UP 2	102
STUDY	.	.
STUDY	.	.
STUDY	FOLLOW-UP x	10x

Understanding evaluation criteria

Continuously evolving



**ACCELERATING RESEARCH &
DEVELOPMENT**