

PP05 Understanding SE, TA, TE Domains

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Submission of the Subject Elements dataset is strongly recommended SDTM IG

Abstract

The FDA clearly request that the subject element table (SE) be part of the submission data. In order to derive the SE domain, the trial domains Trial element (TE), and Trial Arm (TA) also need to be defined and part of the data. This paper will discuss how the Trial domains TE, TA contributes to the derivation of the SE domain and will provide one interpretation of the derivations needed to achieve a compliant and useful SE domain.

Introduction

Subject Elements
The subject element table describes the actual order of elements followed by the subject, together with the start date and end date for each element.

Special Purpose Domains
One record per actual Element per subject
Keys STUDYID, USUBJID, ETCD, SESTDTC

DATA STRUCTURES

- TE – Trial Elements Domain
- ETCD (the companion to ELEMENT) is a required variable.
 - Starting and ending rules for each element.
- TA- Trial Arms Domain
- ARMCD, EPOCH, ETCD, TAETORD are required variables in TA. TAETORD defines the sequence of each element within each Arm.
- SE – Subject Elements Domain
- Planned Element ETCD are variables sourced in TA. If an actual element differ from planned elements ETCD will take the value UNPLAN.
 - TAETORD defines the sequence of each planned element within each Arm.
 - all valid EPOCH are defined in TA.
 - Requirements
 - No gap between elements.
 - Present the chronological order (SESTDTC).

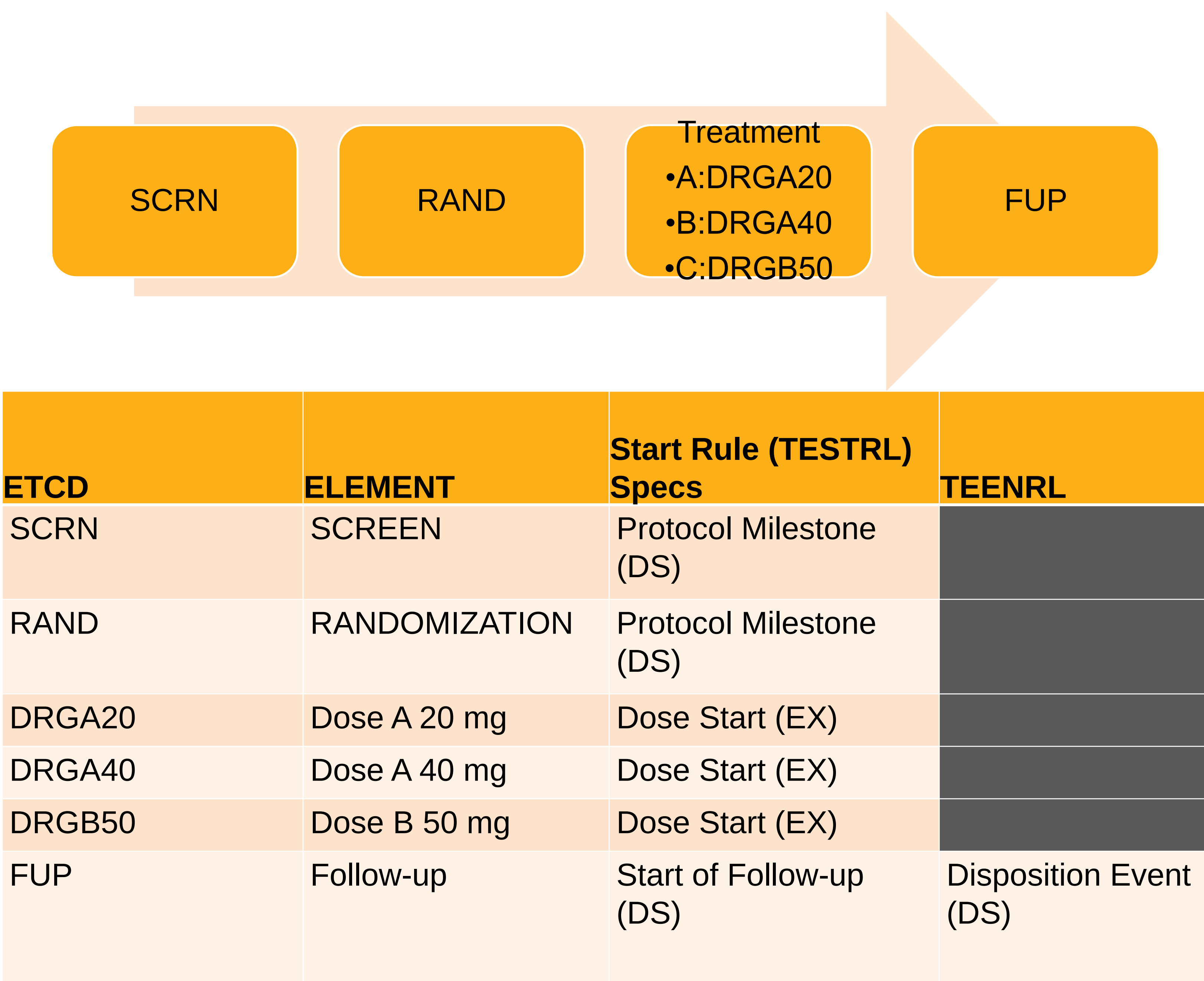
CREATION OF SE DOMAIN

- Evaluate each element start rule in order to make sure the start of an element can be identified programmatically.
- Start with TE and focus on the start date of each elements.
- The end date for the last actual element, if completed.
- Identify the Actual Treatment Elements in 2 easy Steps.

References

PharmaSUG 2015 Papers:
Understanding SE, TA, TE Domains,
J.Lanoue, Novartis Pharmaceutical, NJ

SDTM TE, TA, and SE Domains: Demystifying the Development of SE
Kristin Kelly, Accenture Accelerated R&D Services, Berwyn, PA
Fred Wood, Accenture Accelerated R&D Services, Berwyn, PA
Jerry Salyers, Accenture Accelerated R&D Services, Berwyn, PA



Treatment Element Step -1

Identify the start date of every element defined in TE regardless of the TA-ARMCD definition.

While going thru the exposure data you can identify UNPLAN treatment element
Say a subject received the drug A at a dose level of **60 mg that is not define as a valid treatment**, you could assign ETCD=UNPLAN with SEUPDES="Subject received the drug A dose level of 60 mg".

Arm Treatment Element Step 2

Verify against the subject ARMCD specific plan elements defined in TA.

You can have per example a subject planned to be exposed only to DRGB50 who got exposed to DRGA20. In that situation, you can assign ETCD=UNPLAN with SEUPDES="Subject was exposed to element DRGA20".

COMPLIANCE

The SE domain should be considered as required for a FDA submission. All subjects having completed at least one element defined in TE should be present.
Can be used to populate EPOCH and ELEMENT in other domains.
SESTDTC can't be missing.
No gap exists between elements.
For planned element, the values for the variable ETCD and ELEMENT should match with TE domain.

