Protocol 100000176

Study Design

Study ID	20000109
Trial Description	SAP E2E Study
Trial Type	Double blind Randomized trial
Phase of Trial	Phase II
Status	Ongoing, Specific Countries
Forecast	IRT study with regional distribution
EudraCT	2020-101010-02
First Patient Visit	January 1st, 2020

Double Blind Randomized Trial

The title should be easy to remember, recognizable by administrative support staff, and sufficiently different from other protocol titles to avoid confusion. Brevity with specificity and neutrality is the goal. If there is a "short title" (e.g., an abbreviation used to refer to the study title, include here and that can be used throughout this document in place of the full title).

Protocol Number: 100000176

Principal Investigator: Clark

Sponsor: SAP Innovative Business Solutions

Sponsor means an individual or pharmaceutical or medical device company, governmental agency, academic institution, private organization, or other organization who takes responsibility for and initiates a clinical investigation.

Funded by: SAP

Version Number: v1.0

3 /11/2019

All versions should have a version number and a date. Use the international date format (day month year) and write out the month (e.g., 23 June 2015).

Summary of Changes from Previous Version:

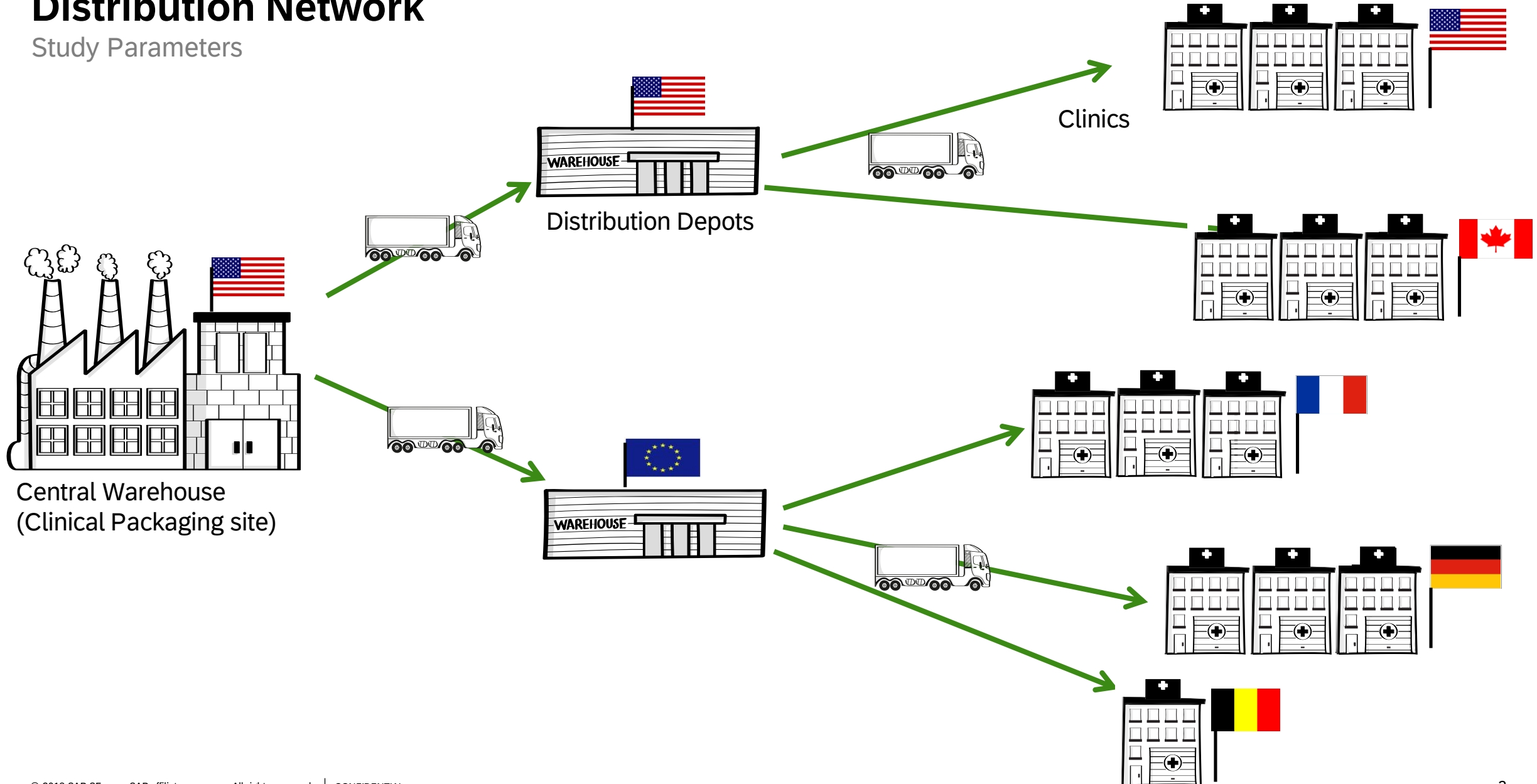| Affected Section(s)	Summary of Revisions Made	Rationale
1	August 31	Draft

Country
Study Parameters

Patient Supply Locations
(e.g. depots, clinics)

Countries	Planned Patients	Planned Sites	First Patient Enrolment	Last Patient Enrolment
Belgium	20	3	02/01/2020	06/30/2020
Canada	50	5	01/01/2020	06/30/2020
France	60	7	03/01/2020	06/30/2020
Germany	80	10	01/01/2020	06/30/2020
United States	200	17	01/01/2020	06/30/2020

Distribution Network
Study Parameters

Distribution Depots

Clinics

Central Warehouse
(Clinical Packaging site)

Treatment Group

Study Parameter

Patients assigned to certain treatment regiment

Study
100000176

Treatment Group 1 High

Ratio 1 (25%)

Treatment Group 2 Medium

Ratio 1 (25%)

Treatment Group   3 Low
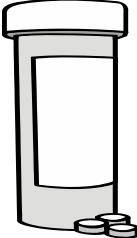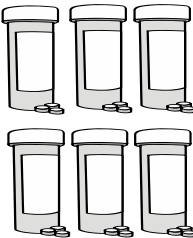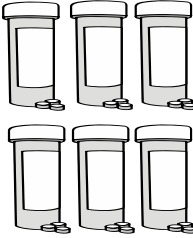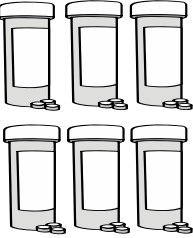
Ratio 1 (25%)

Treatment Group 4 Placebo

Ratio 1 (25%)
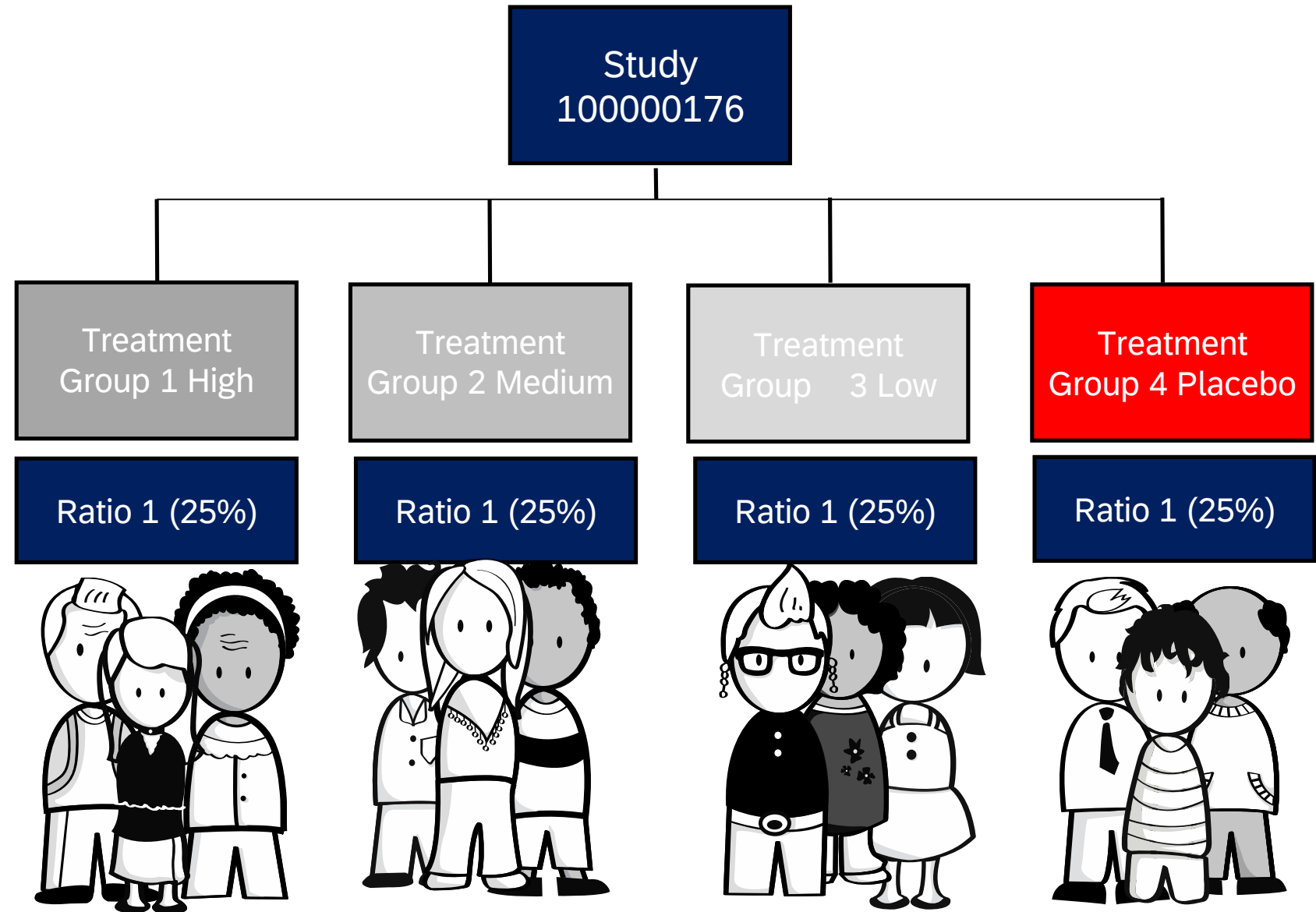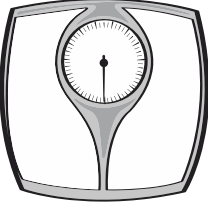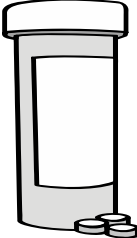
Visit Schedule

Study Parameter

Planned clinic visits for the patient for getting medication and check ups

	Study 100000176					
Visit Period	1	2	3	4	5	6
Phase	Screening	Core	Core	Core	Core	Core
Visit Repetitions	1x 1month	1x1month	1x1month	6x1 month	6x1month	6x1month
Visit category						

Treatment
Study Parameters

Study
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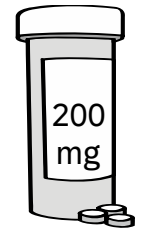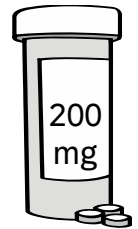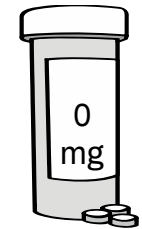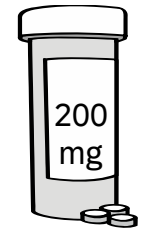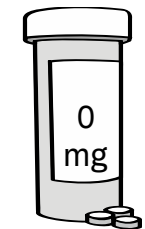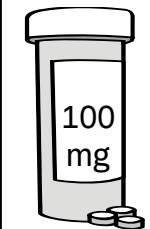
	Treatment 4 400mg		Treatment 3 200mg		Treatment 2 100mg		Treatment 1 0mg	
	Pack type 3	Pack type 3	Pack type 1	Pack type 3	Pack type 1	Pack type 2	Pack type 1	Pack type 1
	200 mg	200 mg	0 mg	200 mg	0 mg	100 mg	0 mg	0 mg
Material no. with Label US/CA	1193	1193	1191	1193	1191	1192	1191	1191
Material no. with Label EU	1188	1188	1190	1188	1190	1189	1190	1190

Medication to be dispensed to the patients

(multiple pack types possible)
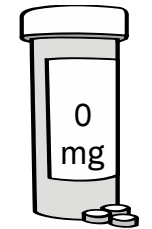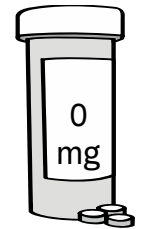
Visit Matrix

Proposed for SAP CTSM suite

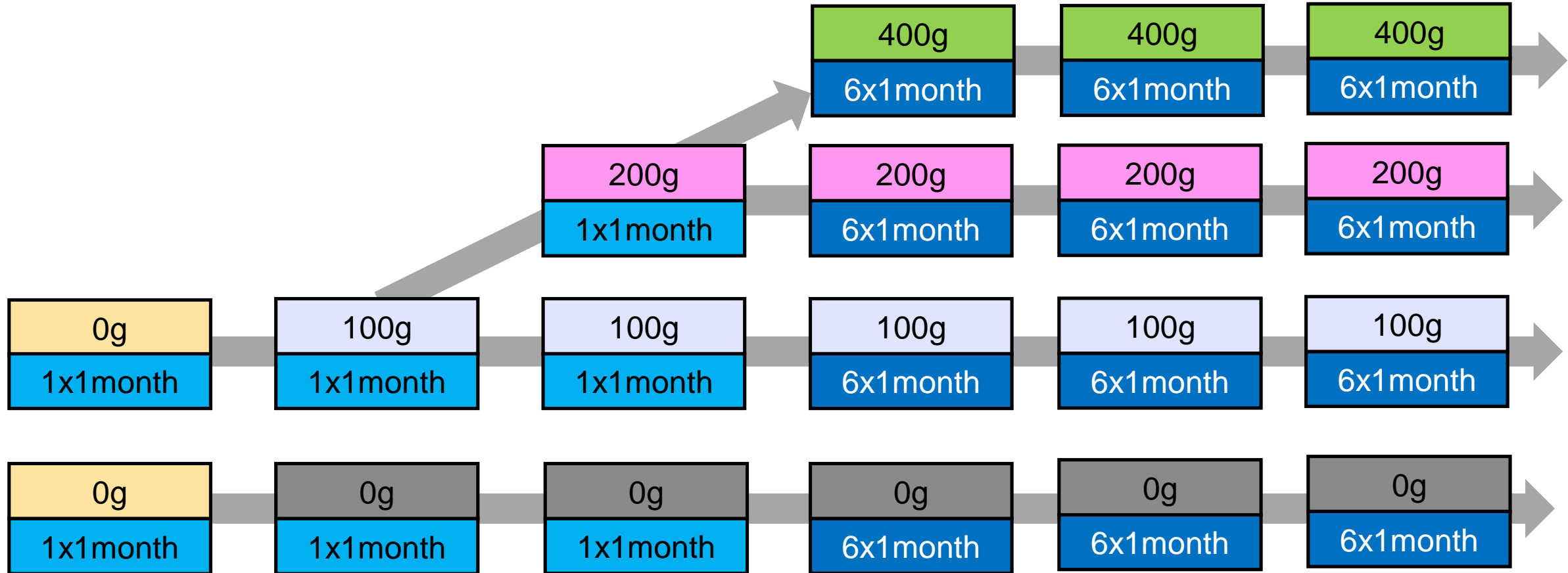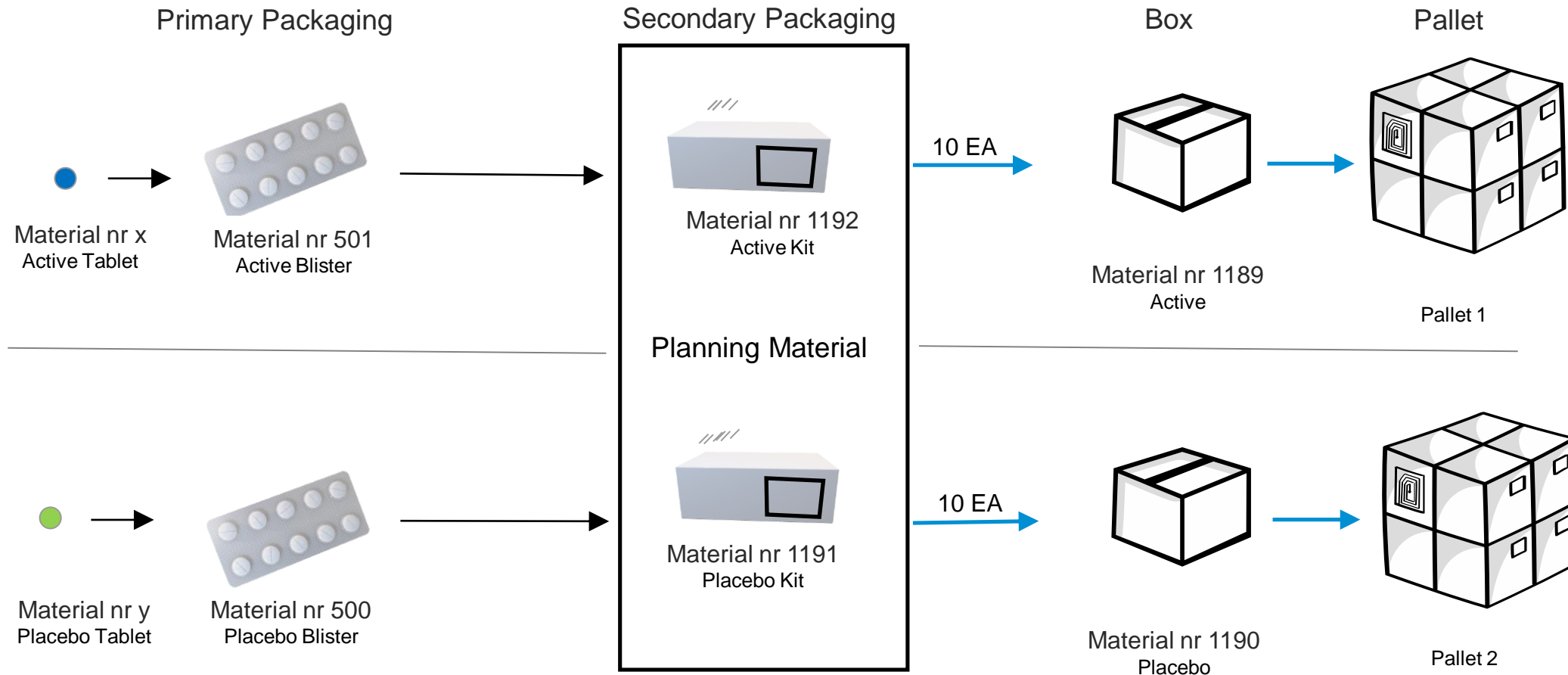|		Prescreening Treatment period 1	Core Treatment period 1	Core Treatment period 2	Core Treatment period 3	Core Treatment period 4	Core Treatment period 5
		1x1month	1x1month	1x1month	6x1month	6x1month	6x1month
Treatment Group 1	High Dosage				Treatment 4 400mg	Treatment 4 400mg	Treatment 4 400mg
Treatment Group 2	Medium Dosage			Treatment 3 200mg	Treatment 3 200mg	Treatment 3 200mg	Treatment 3 200mg
Treatment Group 3	Low Dosage	Treatment 1 0mg	Treatment 2 100mg	Treatment 2 100mg	Treatment 2 100mg	Treatment 2 100mg	Treatment 2 100mg
Treatment Group 4	Placebo	Treatment 1 0mg	Treatment 1 0mg	Treatment 1 0mg	Treatment 1 0mg	Treatment 1 0mg	Treatment 1 0mg

Visit Tree

Study Parameter

Pack Type specific
Serialization Scenario

Primary Packaging	Secondary Packaging	Box	Pallet

Material nr x
Active Tablet

Material nr 501
Active Blister

Material nr 1192
Active Kit

10 EA

Material nr 1189
Active

Pallet 1

Planning Material

Material nr y
Placebo Tablet

Material nr 500
Placebo Blister

Material nr 1191
Placebo Kit

10 EA

Material nr 1190
Placebo

Pallet 2
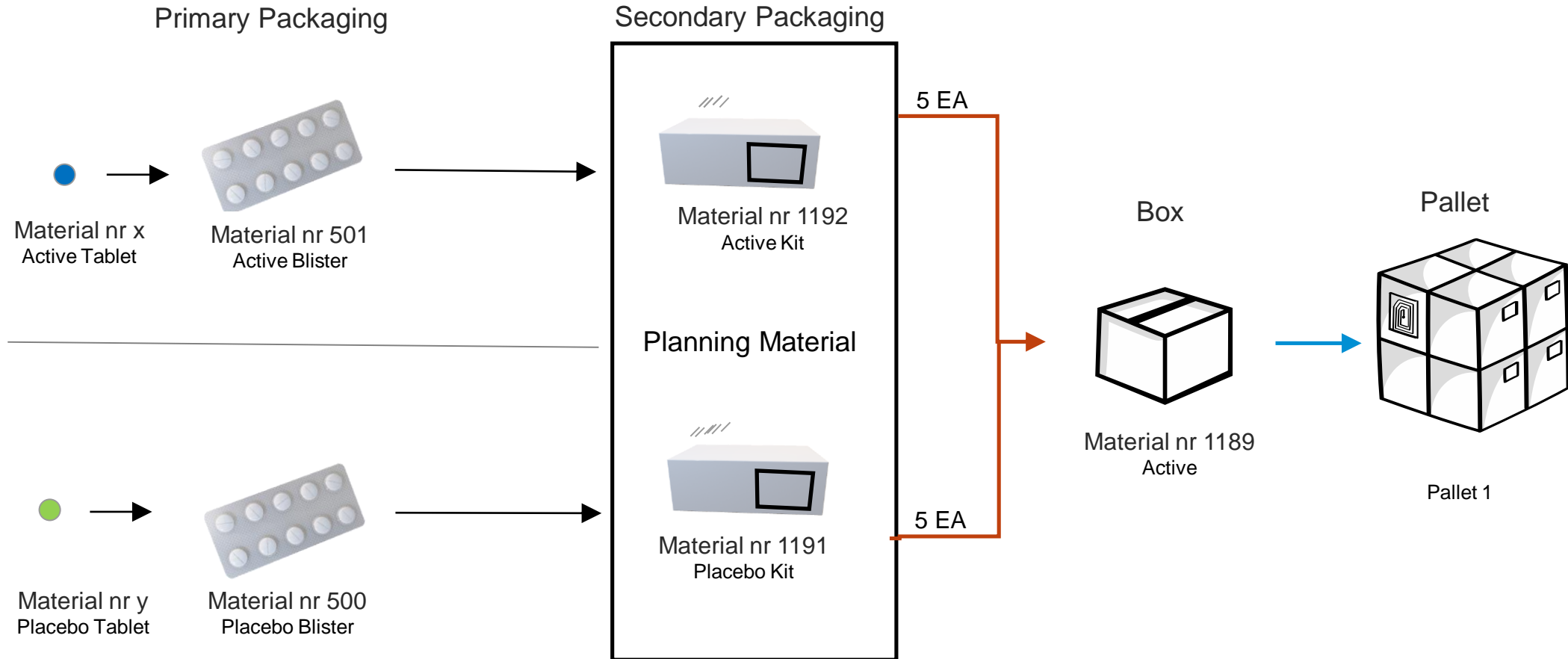
The kit - that is stored and distributed - contains 1 kit type

Kit IDs in the Box are scrambled

The 2 Kit type materials are physically looking identical

Grouped
Serialization Scenario

Primary Packaging

Secondary Packaging

Material nr x
Active Tablet

Material nr 501
Active Blister

Material nr 1192
Active Kit

Planning Material

5 EA

Box

Material nr 1189
Active

Pallet

Pallet 1

Material nr y
Placebo Tablet

Material nr 500
Placebo Blister

Material nr 1191
Placebo Kit

5 EA

The kit - that is stored and distributed - contains multiple kit types

Kit IDs in the Box are sequential and packed in blocks