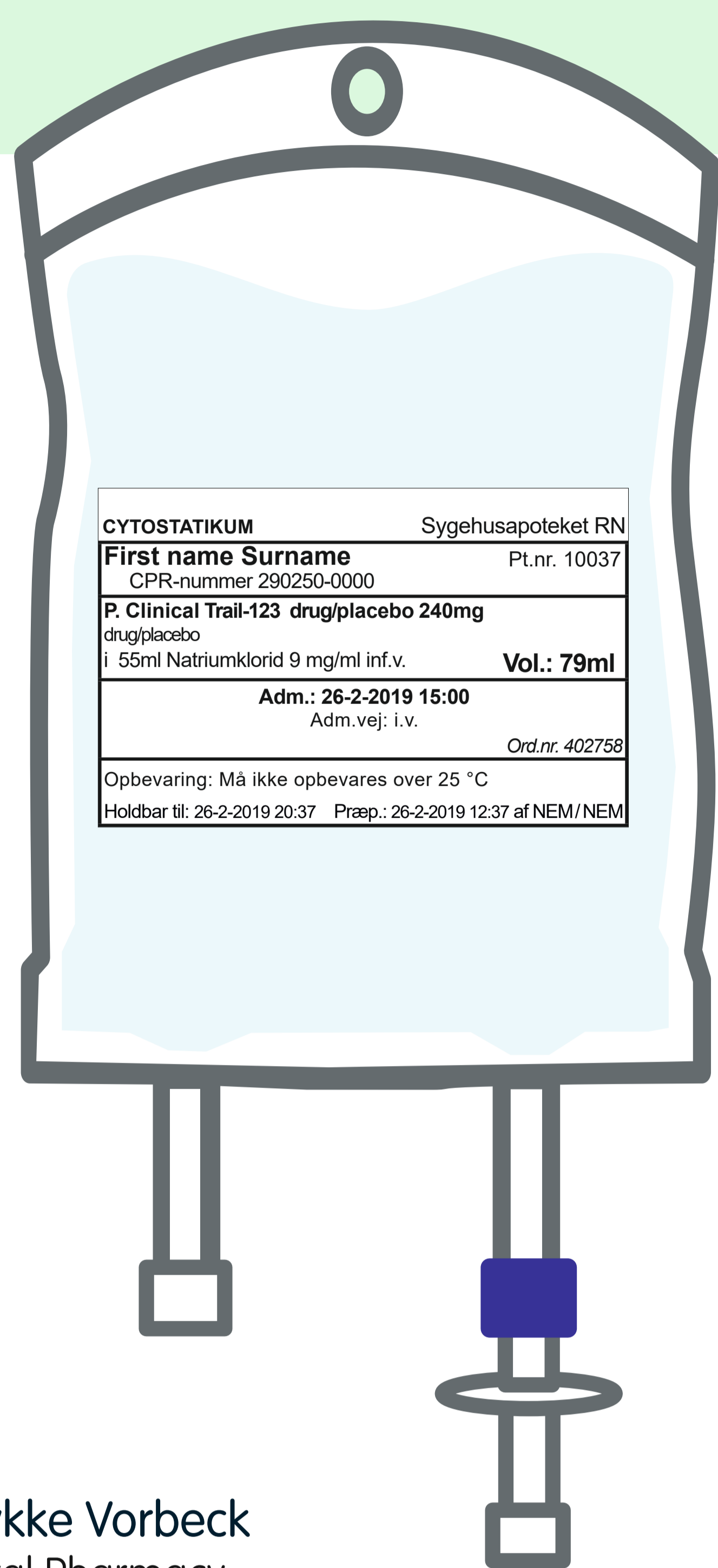
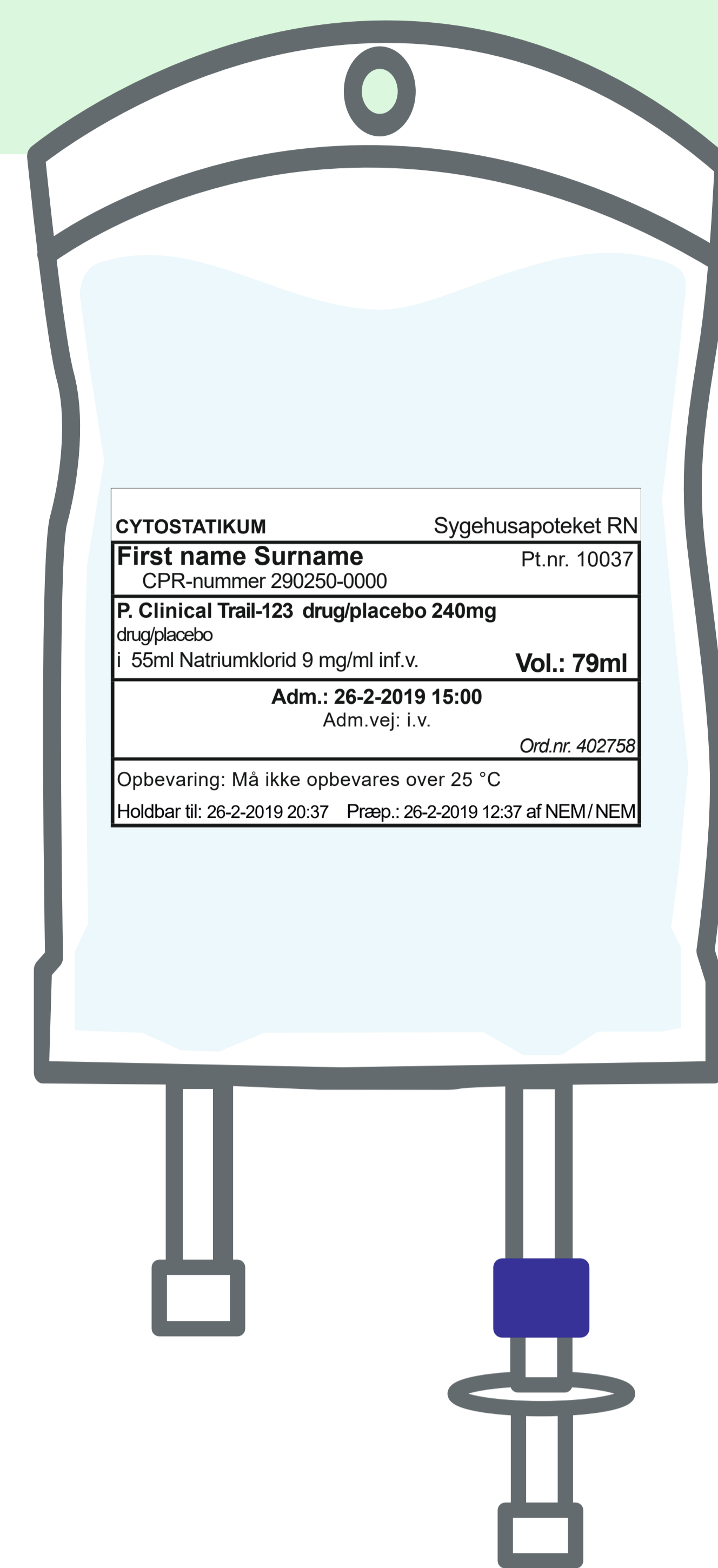


How to handle active and placebo drugs

for a clinical trial in the production system CATO in order to secure the blind and to ensure the exact same preparation of active and placebo products



No difference in label whether active or placebo



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Background

When preparing treatments for blinded clinical trials it is very important to make sure that it is not possible to distinguish between the active and the placebo dose, as this may lead to unblinding of the treatment and thus jeopardise the results of the trial.

Aim

The purpose was to find solutions for how to handle active and placebo drugs in the production system CATO to ensure they would end up being identical when prepared.

Method

Name:

Active and placebo must share the same name for the labels to be identical.
E.g. P.'ClinicalTrial' active/placebo.

Drug data

The drug must be registered in CATO with all of its data. Active and placebo cannot have 2 different sets of data = they must be the same.

NaCl used for placebo will be stocked with data of the active: mass and volume. Density of active can be used for NaCl. Volume of active can be used even if placebo contains a lot more, but CATO will only accept withdrawal of the registered max. volume.

As each lot is stored with its actual weight, although very different, ID of both in CATO is possible.

When placing in storage in CATO, lot no's for placebo are followed by e.g. 'Placebo' to make it easy to see what was actually prepared. Physically, active and placebo are stored together to be treated the same in every way.

- 1 name
- 1 set of data
- 1 place of storage,
- 1 instruction for preparation – active and placebo will be prepared in the same way and look the same.

Result

Our doses of active and placebo are indistinguishable. Labels are the same and, for example, withdrawal into a syringe and insertion of a needle into the port of the infusion bag will be done in the same way for both.

What next?

These very simple routines can be used anywhere for the preparation with CATO and possibly also with other systems.

Volume of placebo is pretended to be that of active.
For identifying in CATO the different total weight of the 2 vials are registered when placing into storage.

batchnummer	Lagerbeholdning pr. 6-3-2019 13:18	Udløbsdato	Beregnet vægt	Stregkode	Studievare
7112081/ PLACEBO	7 stk.	29-2-2020	63840mg	Nej	
7032011/ PLACEBO	4 stk.	31-1-2020	63840mg	Nej	
BATCH NO. / KIT NO. 001	1 stk.	28-2-2020	28520mg	Nej	
BATCH NO. / KIT NO. 002	1 stk.	28-2-2020	28520mg	Nej	
BATCH NO. / KIT NO. 004	1 stk.	28-2-2020	28520mg	Nej	
BATCH NO. / KIT NO. 005	1 stk.	28-2-2020	28520mg	Nej	
BATCH NO. / KIT NO. 003	1 stk.	28-2-2020	28520mg	Nej	

Easy to distinguish active and placebo in stock.

Even if 1 placebo vial contains a lot more than is needed for the dose, placebo is prepared like active, i.e. if 3 vials of active are required for a dose it means that 3 vials of placebo would be required for a similar dose.



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