

Federal agency for medicines and health products

Clinical Trial Regulation EUPD

Pieter Vankeerberghen

1.12.2017

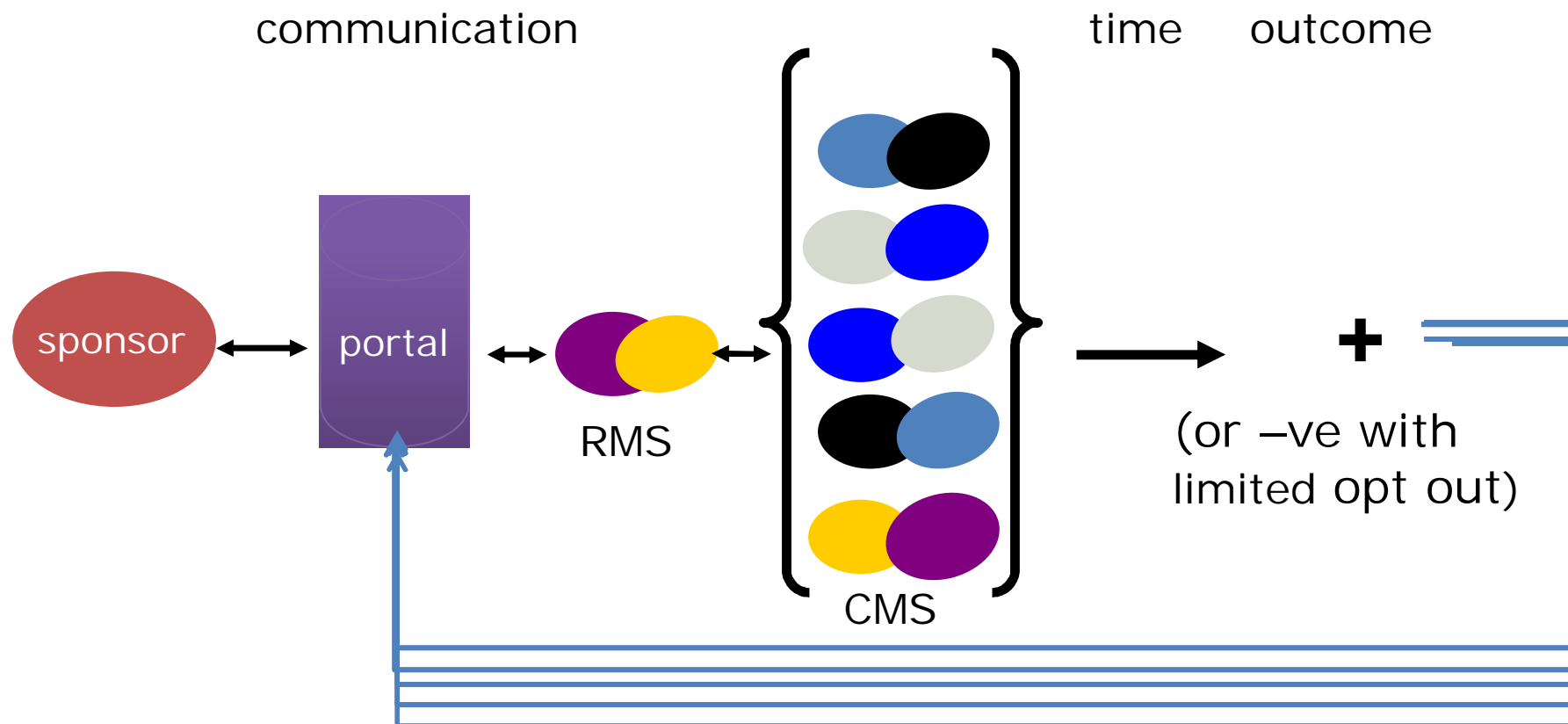


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1. CTR: New simplified procedure in EU



2. Planning CTR in EU



- EU Portal Database (EUPD): status end september 2017: 75% of the auditable and 'must have' scope is implemented.
- Release 6 of EU Portal Database (EUPD) in test beginning Nov 2017. one week onsite testing, one month system available for off site testing.

Results:

core functionality present for a large part, but more attention needed to bug fixing and especially usability.

Approach of on and offsite testing will likely be repeated for further releases

- Relocation of EMA is known (20th Nov 2017).
- EMA to provide further planning.
- CTR expected to go live in 2019.



A large, stylized graphic of a human eye in the background. The iris is a light blue circle with a white pupil. The eyelids are represented by two grey, curved shapes at the top and bottom.

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