

Federal agency for medicines and health products

CTR Pilot objectives 2019

23 January 2019

Objectives for 2019:

- Purpose of pilot is to train sponsors, CTC's, agency, college, Ethics working collectively towards the new regulation.
 - Larger market share of pilot dossiers: more experience and also more performant.
 - In November 2018: already more than 10% of the incoming initial dossiers (for that month) were in the CTR Pilot.
 - Therefore: goals for 2019:
 - In March 2019: that 25% of all incoming initials* are for the pilot
 - In December 2019: that 50% of all incoming initials* are for the pilot
- * including VHP Plus dossiers and including traditional VHP dossiers (outside Collège).



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. The entire graphic is semi-transparent.

**Your medicines and health products,
our concern**