Online supplementary material

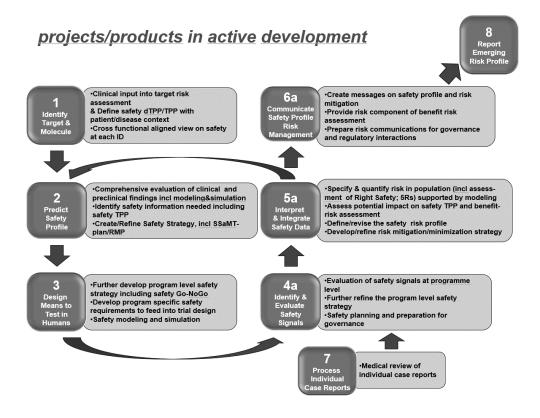
Supplementary Fig. 1: Key activities per value-adding step.

BRAT: benefit-risk action team; CDS: core data sheet; dTPP: developmental target product profile; IB: investigator's brochure; PBRER: periodic benefit risk evaluation reports; PSUR: periodic safety update reports; RMP: risk management plan; SSaMT: safety strategy and management team; TPP: target product profile.

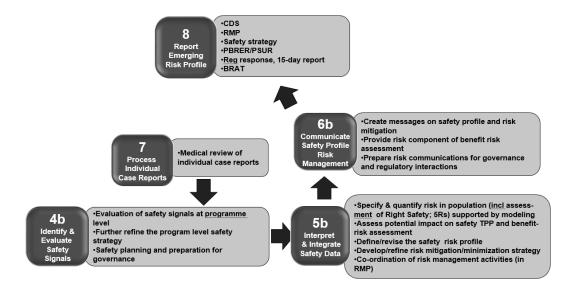
Supplementary Fig. 2: Distribution of rating scores for old vs new documents for each question in the OnePS quantitative survey.

This graph shows the distribution of rating scores that underlies the summary in Table 2.

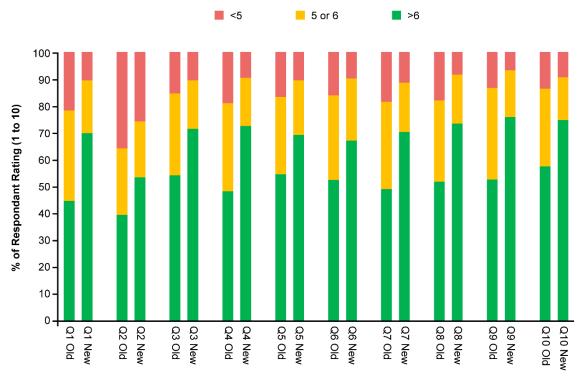
Suppl. Fig. 1.



products post-launch



Suppl. Fig. 2.



Question Responses - Old Documents vs New Documents