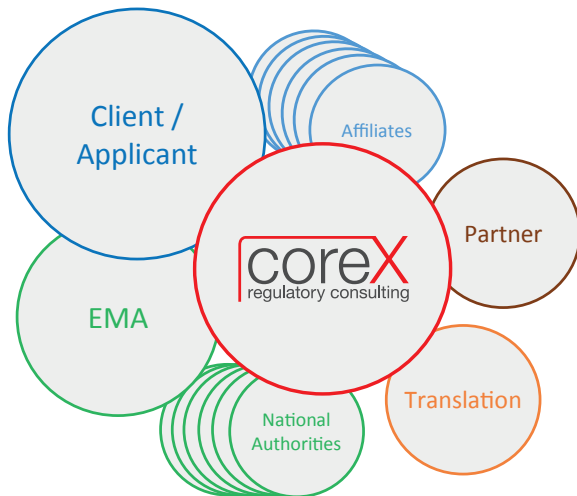


CoreX Interface Function

- ▶ Minimise involvement of client resources
- ▶ Maximise quality of labelling documents
- ▶ Timely and reliable management of the process



Contact

CoreX Regulatory Consulting GmbH
Schwarzwaldstraße 43
79117 Freiburg
Germany

Phone: +49 761 2171 266-0
info@corex-regconsulting.com
www.corex-regconsulting.com

HRB No.: 714389 (Freiburg)

Managing Directors:
Dr. Ruth Rettenmeier
Dr. Thomas Frey
Hans-Joachim Scharfenberg



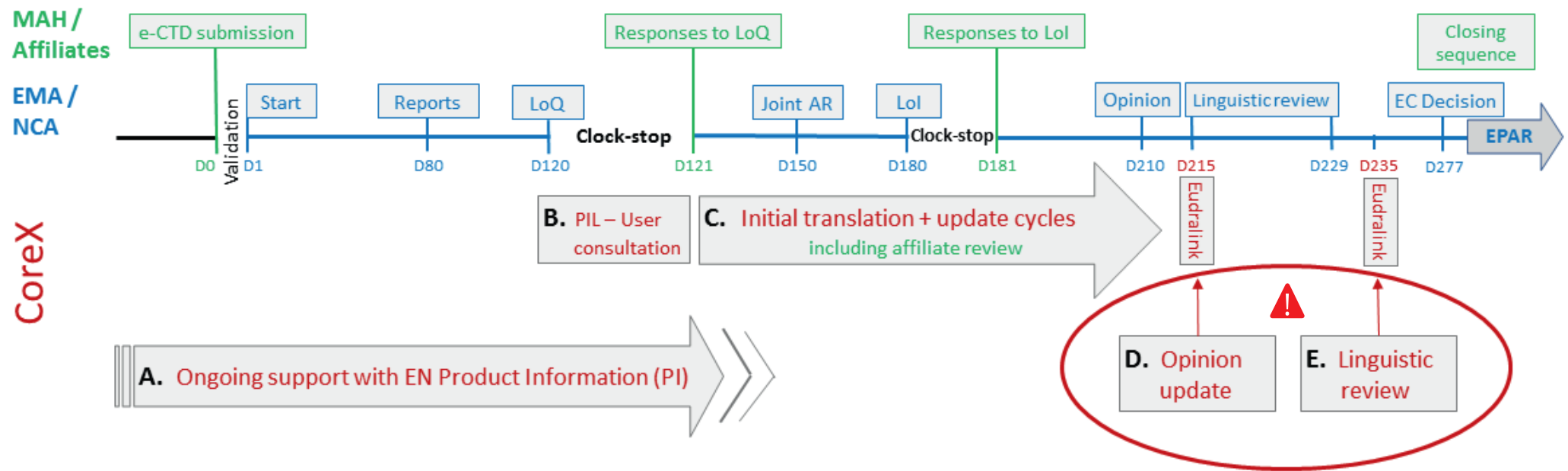
PRODUCT INFORMATION

SmPC / PIL / Packaging Labels

The BUSINESS CARD
of your medicinal product
in all EU/EEA languages



The last 300 days of a centralised MAA ...



... and the CoreX “one-stop-shopping” support

- A. Ongoing support to set up / optimise the English PI prior Day 0 until Day 210
- B. User consultation (readability testing) of the Patient Information Leaflet (PIL)
- C. Day 121 - 210
 - ▶ Initial translation of the English text into 24 EU/EEA languages
 - ▶ Update cycles after Day 181 and prior Day 210 (due to LoQ, LoOI)
 - ▶ Optimisation of language versions (e.g. EMA/QRD requirements; proofreading by a second translator; CoreX regulatory Quality Check)
 - ▶ Management of client’s affiliate review for 24 languages
- D. Day 210 – 215 (over a weekend !)
 - ▶ Update of 24 languages with final EN opinion changes
 - ▶ Day 215 Eudralink submission
- E. Day 229 – 235 (over a weekend !)
 - ▶ Interaction with 24 National Competent Authorities (NCA), during linguistic review
 - ▶ Day 235 Eudralink submission

Individualized strategic and regulatory labelling support for

- ▶ all kind of EU Procedures
- ▶ in all EU/EEA languages

A high-quality and timely service beyond translation