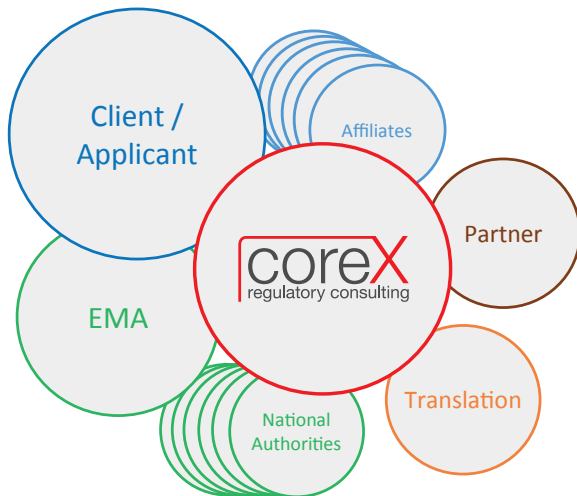


## CoreX Interface Function

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



## Contact

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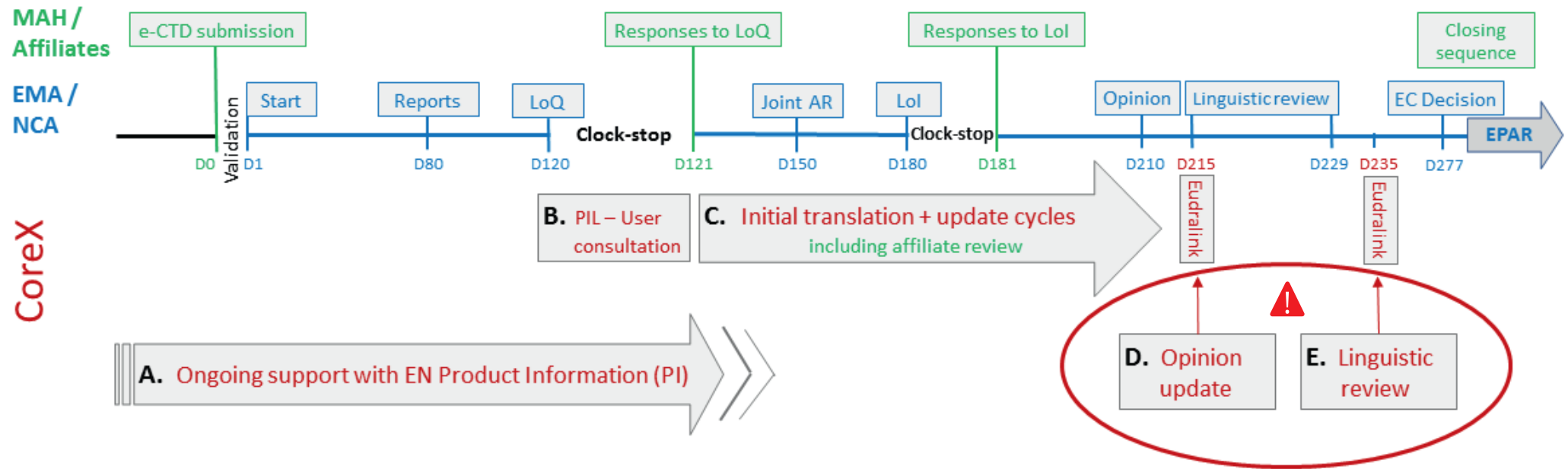
## PRODUCT INFORMATION

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