EMA

Good Clinical Practice (GCP)

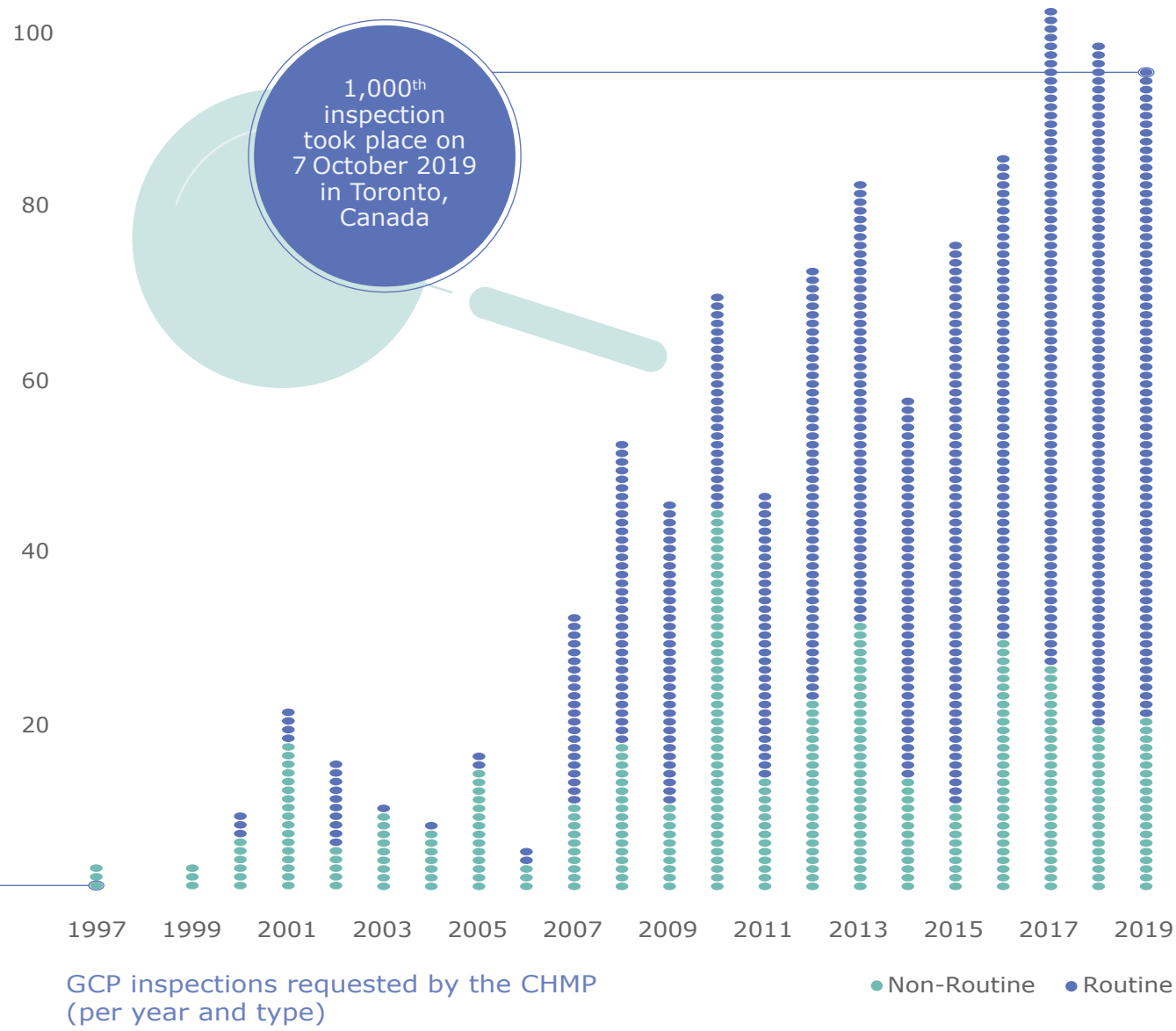
Ensuring international ethical and scientific quality standards for designing, recording and reporting trials that involve people

1,000 GCP inspections

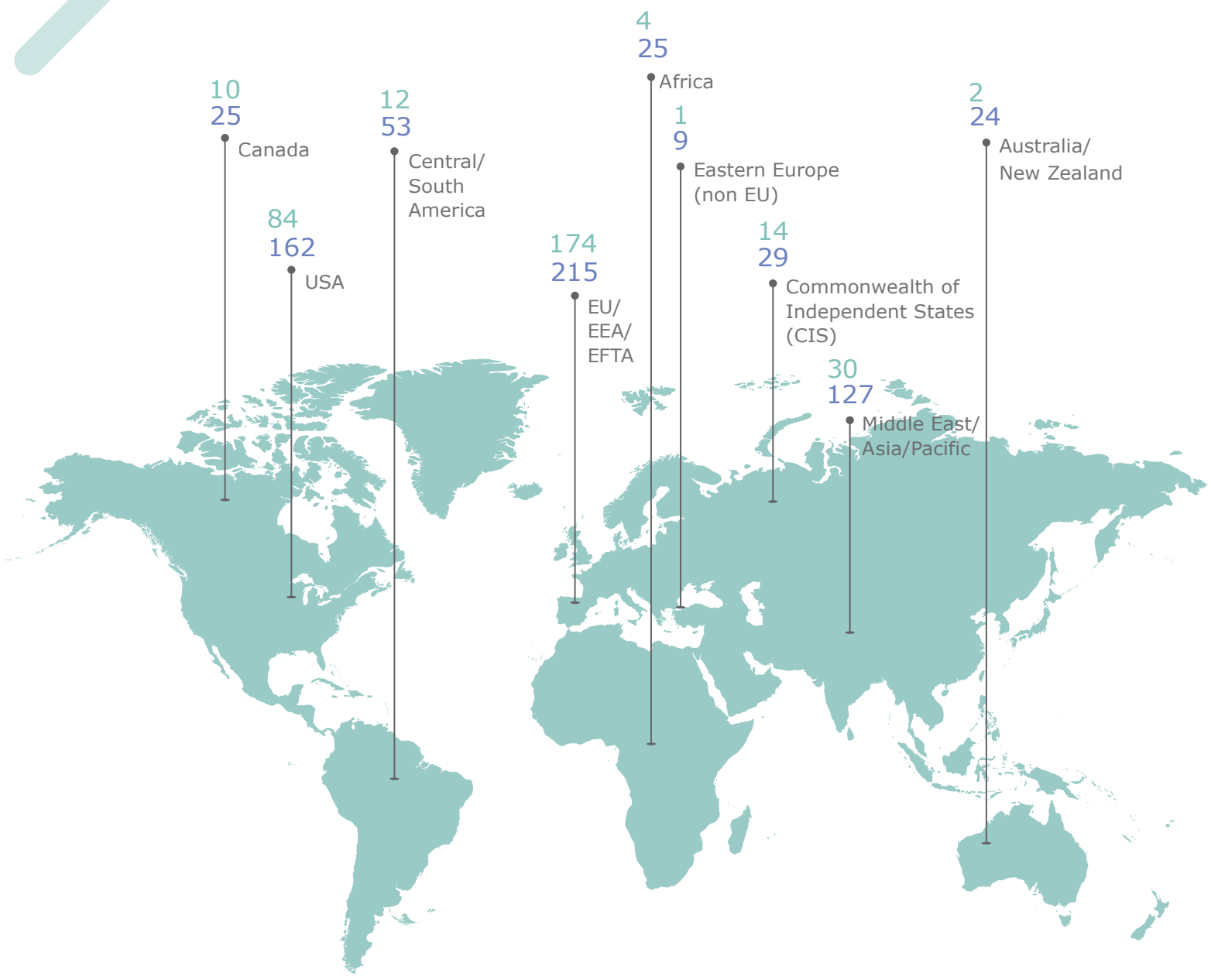
On 7 October 2019, the 1,000th good clinical practice (GCP) inspection requested by EMA's human medicines committee (CHMP) and coordinated by EMA was performed at a clinical investigator site in Toronto (Canada) by inspectors from Austria and Poland.

What is GCP?

GCP is an international ethical and scientific quality standard for designing, recording and reporting trials that involve people. GCP inspections are an essential tool for verifying compliance and providing public assurance that the rights, safety and wellbeing of the individuals who participate in trials are protected, and that clinical-trial data are credible.



GCP inspections requested by the CHMP (per year and type)



GCP inspections requested by the CHMP (per region and type)

Routine inspections:
Carried out as a routine surveillance of GCP compliance, in the absence of specific issues.

Non-routine inspections:
Triggered by issues arising during the assessment of the dossier.