What’s in Your Kit?:
The Medical Translator’s Guide to Navigating Clinical Trials and Investigational Documentation

1. What is the “gold standard” for collecting evidence about the performance of a medical device?
   A. Case series
   B. Randomized controlled trial
   C. Observational study
   D. Integrative study

2. What is a “Notified Body” in European medical device regulation?
   A. An entity of a national government in the EU entitled to grant approval
   B. A private organization accredited by the government entitled to grant approval
   C. The manufacturer labeling the product with the CE marking
   D. A subcommittee of the Directorates-General of Health and Consumers

3. Physicien (FR) means:
   A. Physical therapist
   B. Physician
   C. Physiologist
   D. Physicist

4. Which of these does not belong?
   A. Desinfectado (ES)
   B. Disinfected (EN)
   C. Désinfecté (FR)
   D. Desinfektiert (DE)

5. Documentation necessary to enroll a patient in a trial:
   A. Protocol
   B. Case report form
   C. Informed consent form
   D. Investigator’s brochure