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