RTI HEALTH SOLUTIONS

Considerations for Implementing Surveys Evaluating Effectiveness: Sample Recruitment, Ethics, and Privacy

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Disclosure

- **Affiliation**
  - RTI Health Solutions
- **Conflicting Relationships**
  - No relationships to disclose

Feasibility Considerations to be Discussed

- **Potential Sources of Data**
- **Target Countries**
- **Target Population**
- **Sample Recruitment**
- **Modes of Data Collection**
- **Ethics Submissions**
- **Privacy**

Understand Potential Sources of Data

- **Prospective Studies:**
  - Patients
  - Physicians
- **Retrospective Studies:**
  - Charts/Electronic Medical Records
  - Databases
  - Registries
- **This presentation will focus primarily on prospective patient surveys**

Target Countries

- **Determine the countries in which you plan/need to collect data**
- **Considerations**
  - Research differences in treatment practices
  - Determine ethics committee requirements
  - Identify sponsor affiliates and/or clinical experts located in each country of interest

Understand the Target Population

- **Considerations**
  - What are the disease characteristics?
  - What are the treatment characteristics?
  - What are the characteristics of the treating population?
  - What are the patient demographics?
- **Estimate an appropriate sample size**
- **Determine your inclusion/exclusion criteria**

Recruitment Strategies-Physicians

- **Recruitment sources**
  - Sponsor lists
  - Web panels
  - Professional scientific societies
- **Considerations**
  - Overall representativeness of target population
  - Accuracy and completeness of the information
  - Geographic location, physician specialty, and patient mix to obtain diversity among sites
- **PI or professional society may endorse study to facilitate recruitment**

Recruitment Strategies-Patients

Design	Description	Pros	Cons
Clinic-based	Recruit a sample of physicians to prospectively identify eligible patients for survey as they come in for routine visits	Assured of patient eligibility; higher response rate; patients are approached at time of visit and physician lends credibility to study; patient can't prepare by re-reading educational materials beforehand	Potential for bias as some HCPs may provide additional education to participating patients
Health-care database	Identify patients in the database meeting the study criteria and contact them to participate in the survey	Database can be searched for specific inclusion or exclusion criteria; clinical data are available; ability to compare respondents to nonrespondents.	There is a lag time in data; however, data are becoming more current
Web panel	Recruit patients via an existing Web panel by e-mail	Efficient method for accessing large groups of people who are available to complete surveys	Data are self-reported and are not confirmed by a physician; may lack sufficient quality assurance standards to meet reporting requirements; patients may prepare beforehand; must be a commonly used drug
Patient advocacy groups	Work with established patient advocacy groups to invite their members to participate in the survey; the feasibility of this approach depends greatly on the cooperation of the individual support groups	May be a good option for otherwise hard-to-reach patient populations	Potential for bias as patients may have more severe disease or have received additional education about their medications

Modes of Data Collection

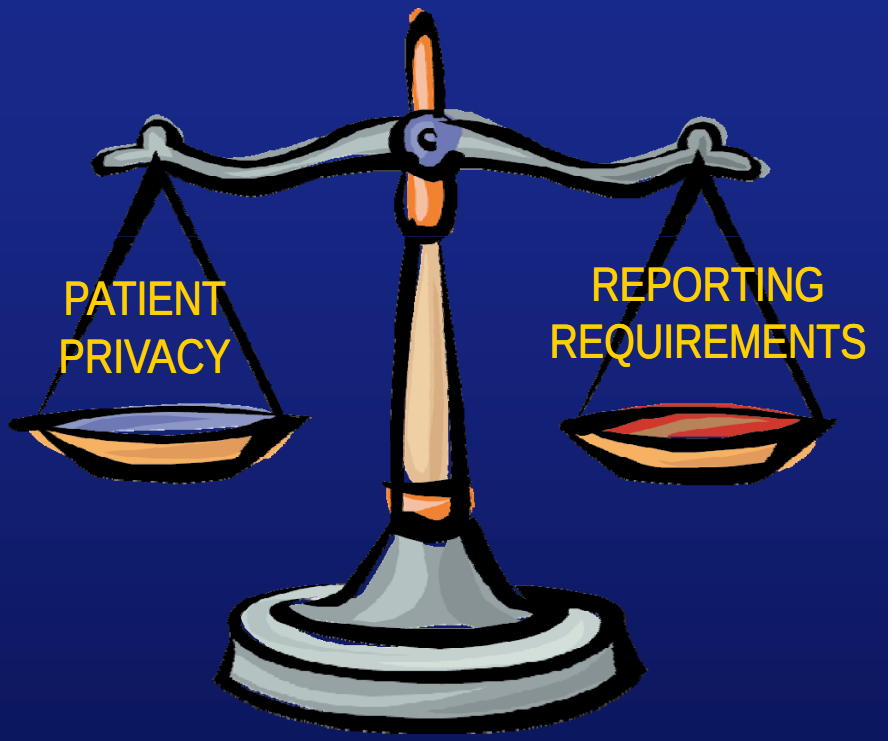
- **Web**
- **EDC**
- **Telephone**
- **Paper**
- **Handheld diary**
- **IVRS**
- **Fax**
- **Mixed modes**

Ethics Committees

- **Not harmonized across EU countries**
- **Differences in requirements, process, and timing**
- **PIs can facilitate the EC submission and approval process**
  - Provide guidance on requirements or reach out to ECs to inquire on guidelines
  - Review submissions
  - Attend meetings
- **Documentation that links the study to the EMA request for RMP evaluation may facilitate approvals**

Privacy

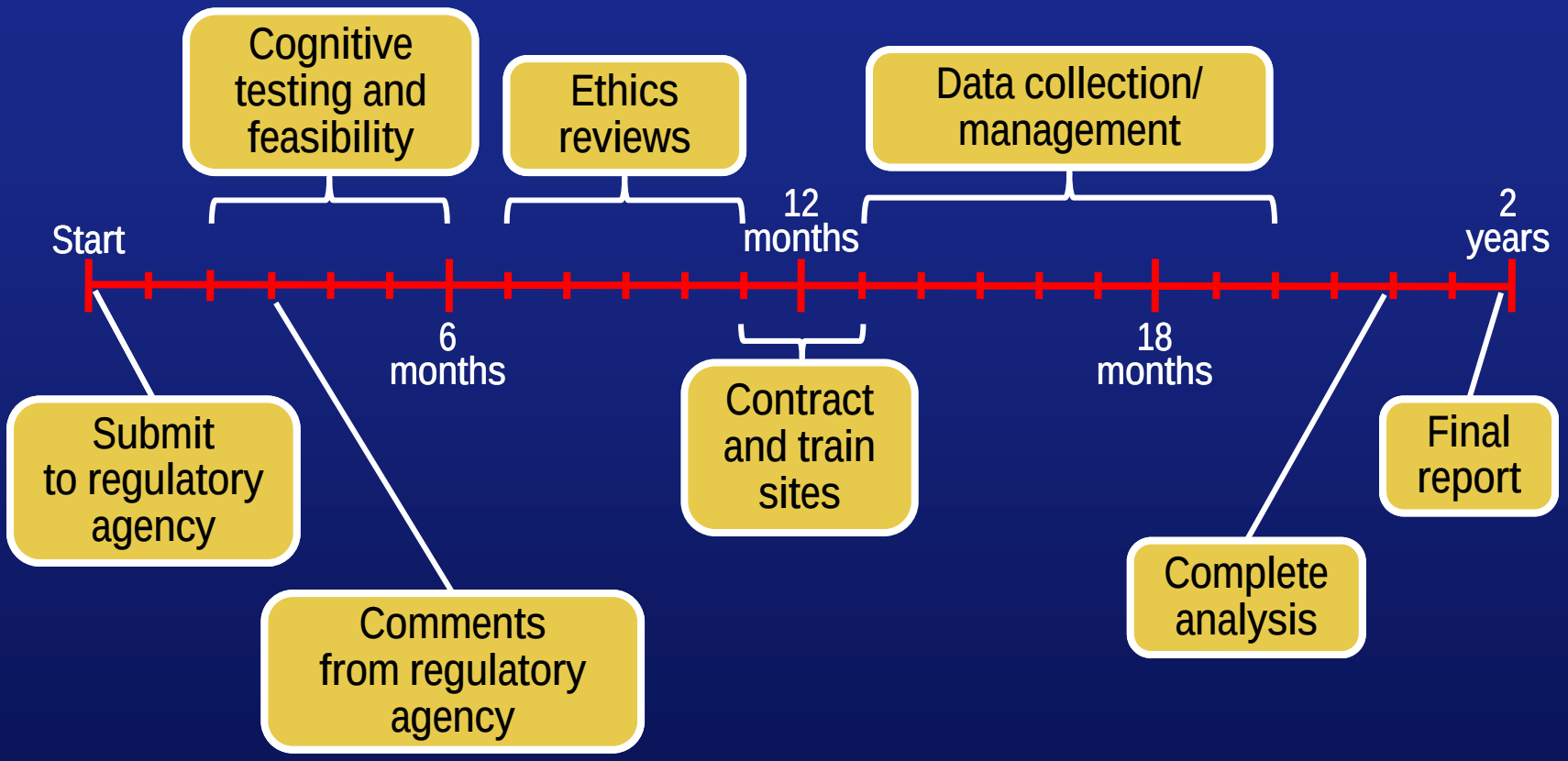
- **Obtain informed consent**
- **Collect only de-identified data**
- **Employ methods to encourage participants to respond honestly**
- **Assure patients' privacy when reporting adverse events**



Feasibility Assessments

- **Gather information on site and patient characteristics**
- **Estimate reasonable patient sample size, number of sites to achieve sample size, and approximate length of data collection period**
  - Based on estimated patient volume, frequency of patient visits, and expected patient response rate (as estimated by sites)
- **Evaluate site resources, patient flow, and patient counseling practices**
  - Confirm whether survey can be completed at the site prior to the patient receiving additional counseling on medication
- **Assess site interest in the study**

Timeline Example



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Thank you