

Day One Wrap Up

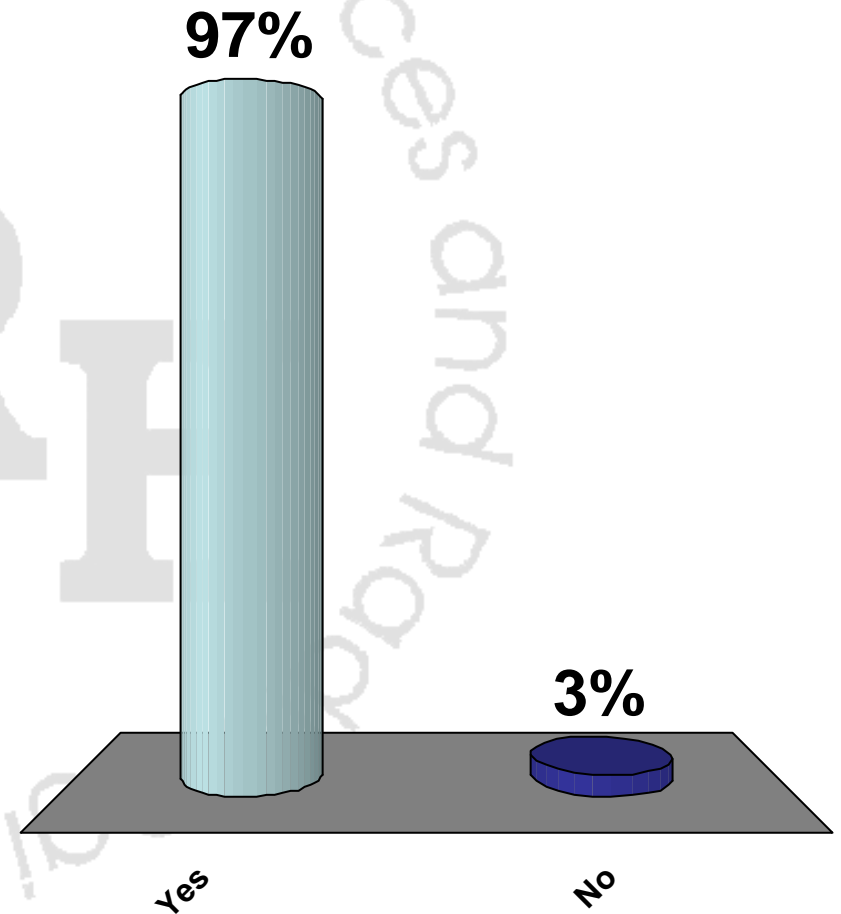
Philip Desjardins, JD
Nada Hanafi, MPH, MSc

1. Open Public Comment Session
2. Audience Participation
3. Summary of Day One

Is your clicker working?

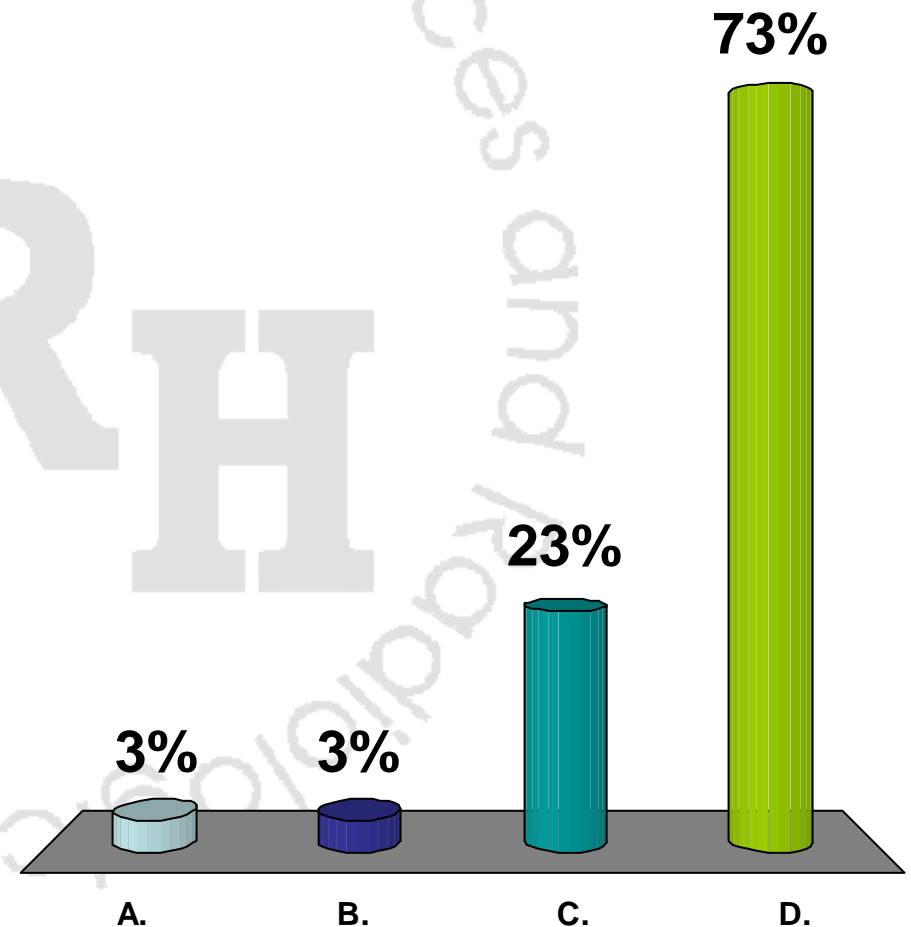
A. Yes

B. No



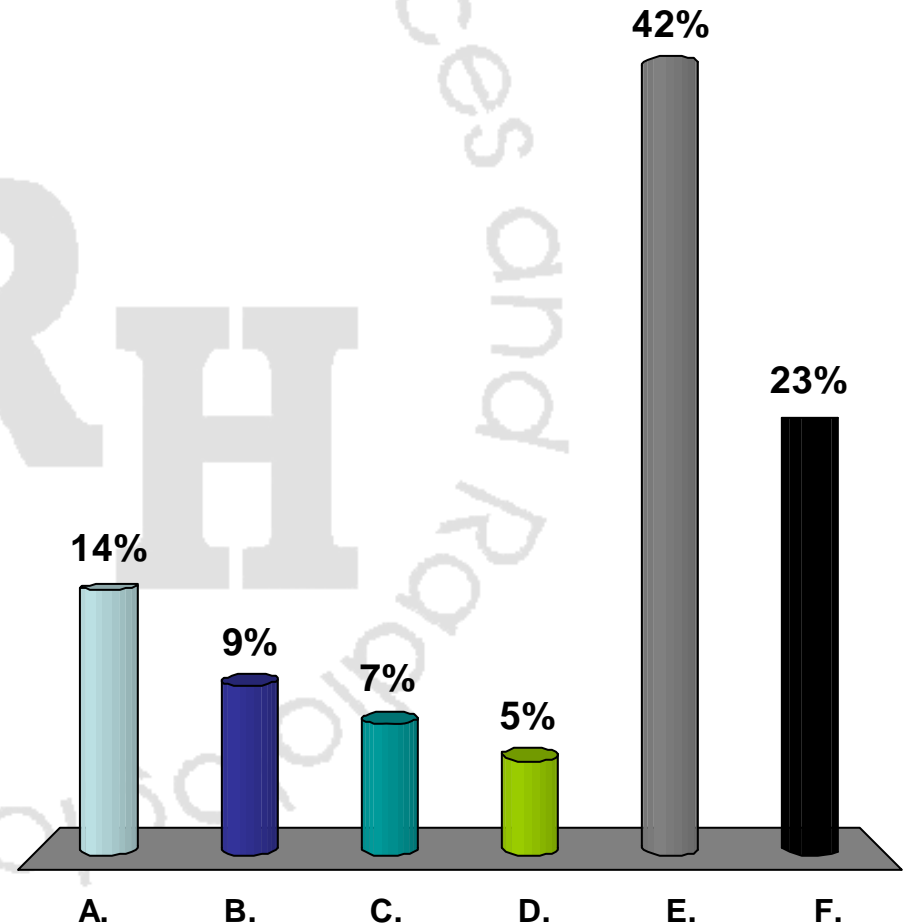
When did FDA begin developing a unique regulatory framework for medical devices?

- A. June 1906
- B. June 1938
- C. January 1976
- ✓ D. May 1976



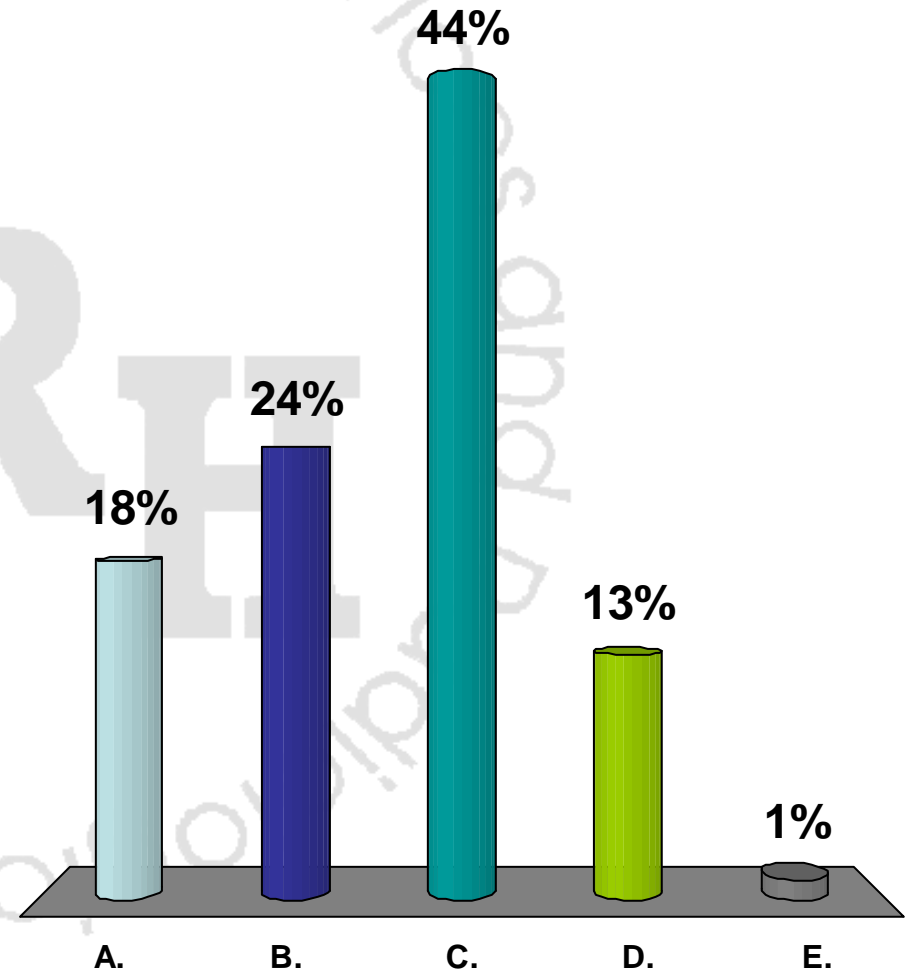
Please identify your affiliation:

- A. Patient/ Patient advocacy group
- B. Professional Society
- C. Research/ Academia
- D. Provider/Clinician
- E. Industry
- F. Federal Agency



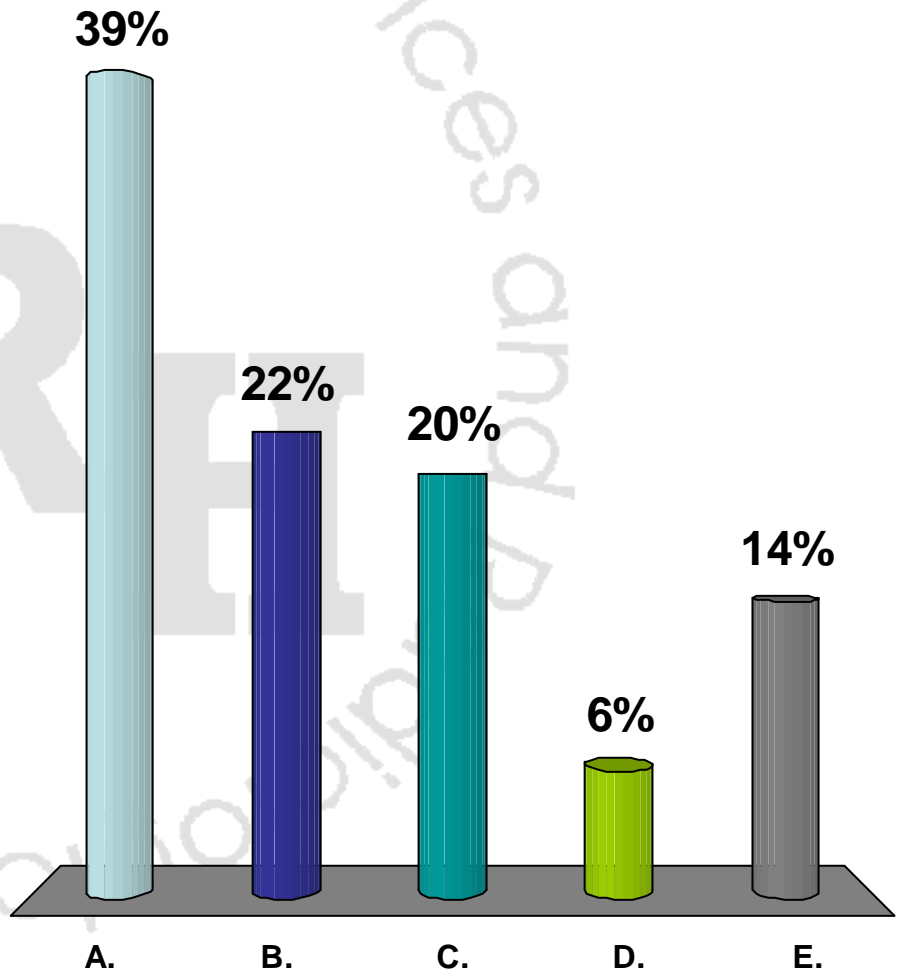
From who is patient preference information most valuable?

- A. Newly diagnosed patients
- B. Patients who have exhausted their clinical options
- C. Patients in the middle of their disease
- D. Caregivers/Parents
- E. General public



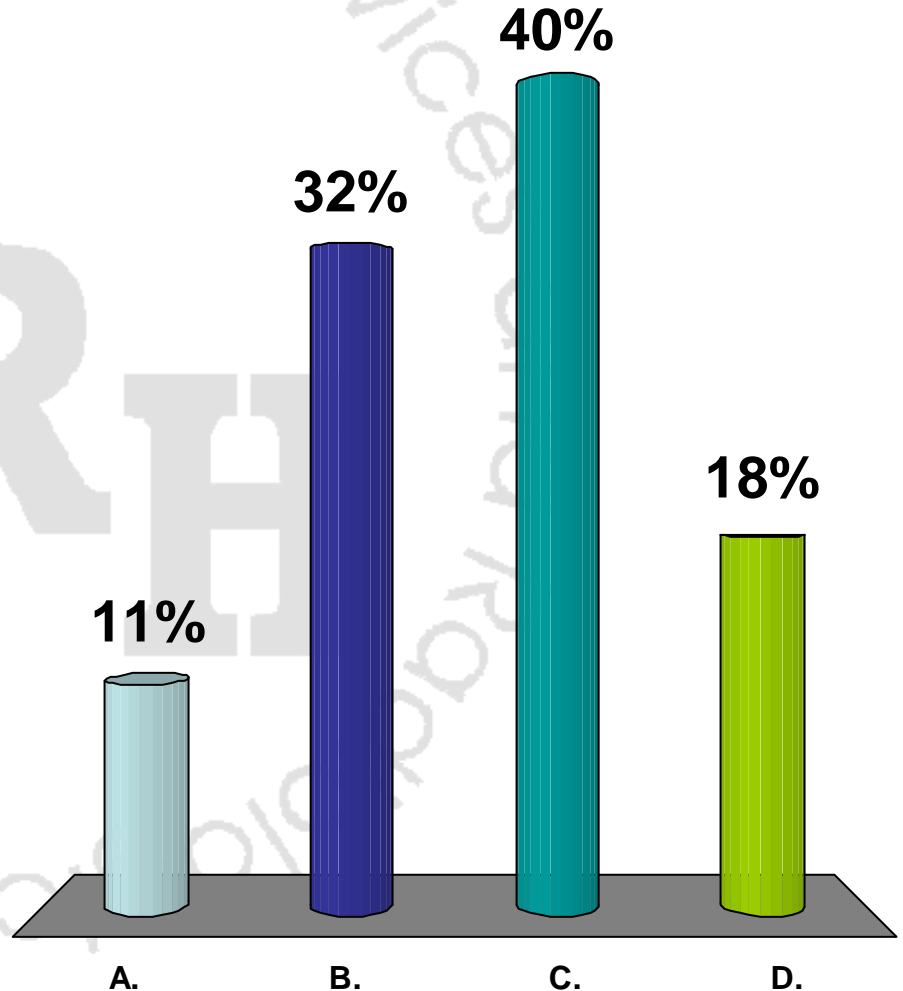
Where can patients be found?

- A. Patient advocacy groups
- B. Online forums
- C. Health insurance companies
- D. Open solicitations from FDA
- E. Open solicitations from non-FDA stakeholders

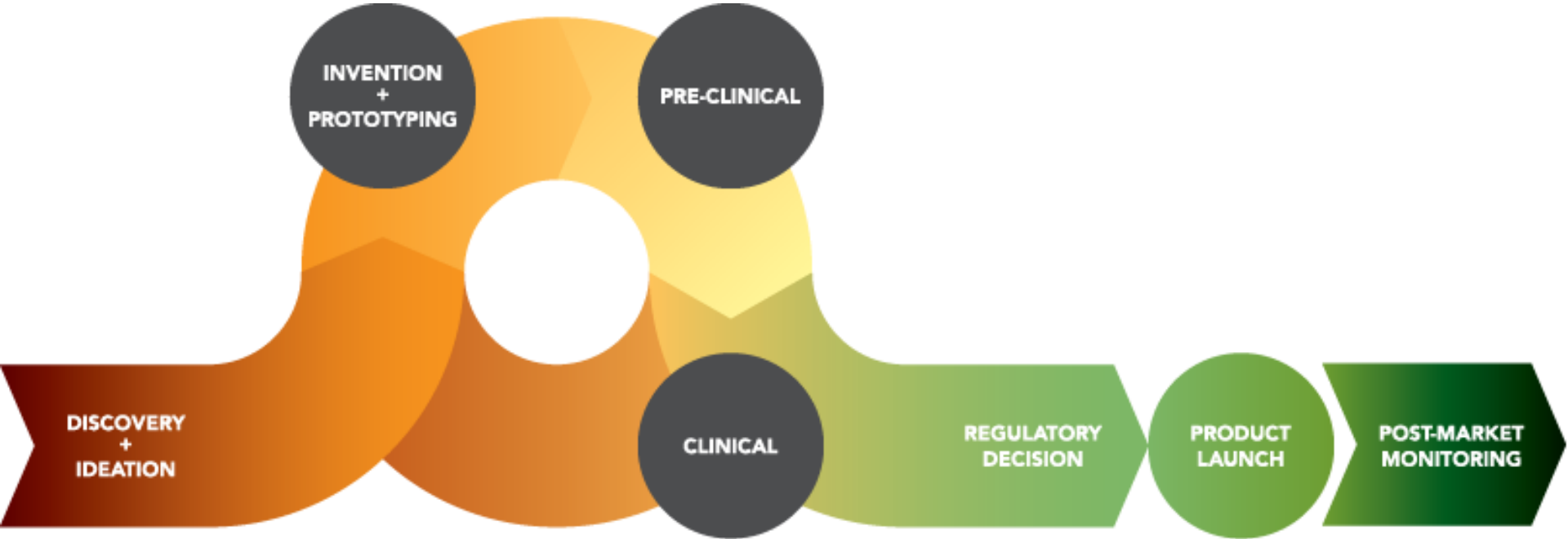


How can patient preference information be collected?

- A. Surveys – in person
- B. Surveys – focus groups
- C. Online surveys (internet approaches)
- D. Social media/data mining

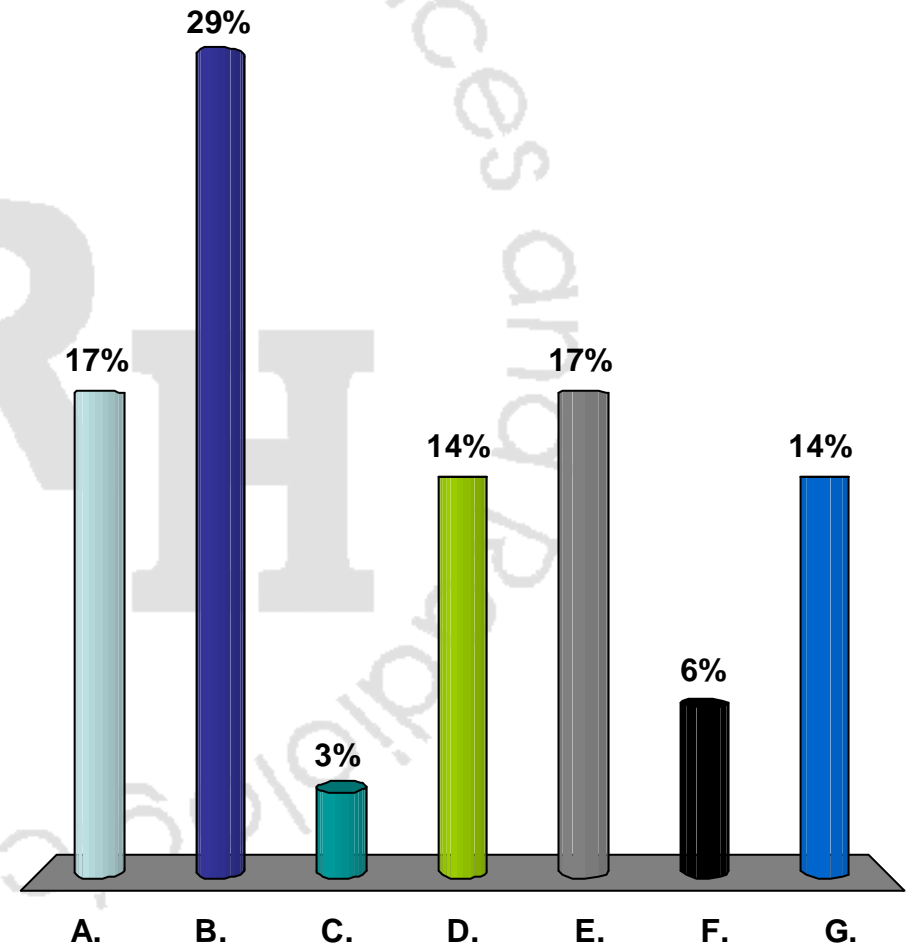


The Total Product Lifecycle



Where in the medical device total product lifecycle (TPLC) could you see patient preference information best utilized?

- A. Discovery & ideation
- B. Invention & prototyping
- C. Pre-clinical
- D. Clinical trials
- E. Regulatory decision
- F. Product launch
- G. Post-market monitoring



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