Healthy Volunteer Studies in Oncology Drug Development (ODD): Pivotal Considerations Toward Optimal Deployment

ASCPT Symposium

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Traditional Considerations in ODD

- Oncology drugs are too toxic to be tested in healthy volunteers (HV)
- PK in HV does not translate well to PK in oncology patients (i.e. target-mediated CL)
- Direct to Patient studies offer competitive advantages:
  - evaluation of early signals of efficacy
  - role of biomarkers: i.e. receptor occupancy, translational oncology
  - potential for a single, well-designed and adequately powered study to become registrational

Emerging Considerations

- Too many oncology drug trials and too few available patients
  - Logjam caused by companies hoping to rush ahead of competition
    - 2018 ASCO-SITC symposium:
      - > 4,000 ongoing IO trials;
      - ~1,500 combo IO trials; requiring > 150,000 patients
  - Expand access to trials for traditionally excluded patient populations
    - Minimize risk from extrinsic and intrinsic factors: i.e. DDIs, organ impairment
- Patient-centered drug development:
  - Maximize potential for benefit, minimize safety/tolerability risks
    - Minimize risk from inadequate or too high dosing
    - Informed consent
      - Evidence & reliability of data that a treatment will actually work
  - Minimize assessment burden