1. We have discussed the ethical and logistical constraints associated with obtaining the first-in-human experience using novel devices to treat life-threatening bleeding. Considering these constraints, in what patient group can testing start? What are the pros and cons of performing testing in this group of patients?

Group 1

- Do not exclude 95%
- SURGEONS To medics with no experience (may have not used new device)
- FDA look for intermediary steps
- Come together for efficacy FDA - early discussion and interaction with e.g., NIH

Group 2

- 50.24 studies approach difficult to generalize, product types different and difficult to compare
- Studies without consent on limited basis –
- Benefits- controlled setting for sufficient data for feasibility (by video), protocol and community development
- OUS? Same ethical and documentation issues, but differences in documentation/ standard of care

Group 3

- Understand intended use and based on this understand intention and, clinical relevancy for model determined
- Looking for feasibility – any patient, look at just performance criteria for feasibility to be successful
- Controlled operation room setting

Group 4

- Traumatic injuries – high risks patients, similar approach to XStat
- Post-market studies, start with soldiers on battlefield
- Then 510k for general population

Group 5

- Patient groups

    - ED
    - Military
    - Elective procedures – ethical considerations for those procedures
- Wrong Question? – does it need human testing and define what human testing is.

Group 6 – no consensus

- Early Feasibility study – IDE
- 50.24 – timeline
- 5 patients, how device works, feasibility
- Post-market studies – FDA control with post-market, to gather info on feasibility
- Final solution will be in middle – benefits and risks of all patient populations to consider

<u>Comments:</u>

Pre vs Post-market setting – evidence of performance ?

Pre-market burden shift to post-market?

Continue to focus on post-market peer-reviewed data

Depends on what will be tested and how product used. Some may not be appropriate for post-market testing.

Does it need human testing? Risk-benefit profiles: any intervention or device to specific population will dictate how have initial human experience.