Pre-Clinical Overview

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Pharmacology/Toxicology Development Considerations

- Not feasible to conduct animal studies for all potentially relevant combinations
  - DAA + SOC and other DAAs
- Combination toxicology studies not needed
  - More useful to have studies with individual agents at multiple and higher doses
- To support human trials for up to 90 days for 2+ DAAs:
  - For each DAA need:
    - Need minimum of 3 months repeat dose nonclinical toxicity studies in rodent and non-rodent
    - 6 month rodent, 9 month non-rodent can support longer duration combination trials, depending on toxicity profile
- Nonclinical studies of DAA + SOC not needed unless data suggest potential for increased or synergistic toxicity with approved agents