A Lifecycle Approach to Structured Benefit/Risk Assessment
The voice of patients can play a critical role in helping to better inform the search for treatments and cures for chronic and deadly diseases throughout drug discovery & development.

When sponsors develop proposed frameworks based on patient input and proactively share it with FDA at key stages in drug development and review, the framework becomes an evolving document that can serve as a decision-support tool to help guide benefit-risk discussions across a product’s lifecycle.
Opportunities for Structured Benefit/Risk Assessment during Drug Development

Assess patient group views on:
1. Analysis of Condition
2. Treatment Options

Share clinical data confidentially with patient groups and seek feedback on:
3. Benefit
4. Risk
5. Risk Management

Provide Advisory Committee Members with sB/R in briefing document to frame the meeting

Phase 1
Pre-IND Mtg
Align with FDA on Condition & Treatment Options

Phase 2
EoP1 Mtg
Sponsor submits sB/R to FDA align on B/R considerations

Phase 3
EoP2 Mtg
Sponsor submits sB/R with NDA/BLA

FDA Review
Pre-NDA

Phase 4
Late-Cycle Mtg
FDA Posts Final sB/R

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