The ADAPT model has 5 tangible and easily implemented levers with easily defined expected outcomes and response requirements. To reflect ADAPT in everyday practice, we developed an integrated operational solution:

**An integrated patient-centric development plan, when applied to rare and orphan medicinal products (OMPs), can accelerate time to market by 12 to 36 months.

- **Integrate evidence**
  - Drive required data collection and evidence generation
  - Quantifying the potential substantial benefit for patients
  - Increased availability for patients
  - Evidence vs. access conundrum

- **Incorporate patient and family input**
  - Partner with all key stakeholders early and through project
  - Anticipate and plan for clinician and patient unknowns
  - Provide opportunity to voice concerns and experiences
  - Facilitate communication between all parties involved

- **Incorporate a competitive landscape**
  - Competitive landscape and arrangement for the benefit of a patient
  - Efficient integrated post-approval and follow-up

- **Incorporate a commercialization strategy**
  - Segmentation and opportunity readiness
  - Detailed barriers to overcome to approval, reimbursement
  - Opportunities to:
    - Drive required data collection and evidence generation
    - Quantifying the potential substantial benefit
    - Increased availability for patients
    - Evidence vs. access conundrum

- **Incorporate a competitive landscape**
  - Competitive landscape and arrangement for the benefit of a patient
  - Efficient integrated post-approval and follow-up

**Examples of the levers in action**

**Integrate evidence**

- **Faster, smaller, targeted clinical development**
  - Up to 3 years
  - Applied to rare and orphan medicinal products (OMPs)
  - Accelerated regulatory pathways & early access tools
  - 6 months to 3 years

- **Medicines adaptive pathways**
  - 1-2 months

- **Agreed consensus on definitions and diagnosis**
  - 2 years

**Incorporate patient and family input**

- **Conditional MA**
  - ~4 years

- **Early scientific advice**
  - 49 to 210 days

- **Accelerated regulatory pathways & early access tools**
  - 6 months to 3 years

**Incorporate a competitive landscape**

- **Competitive landscape and arrangement for the benefit of a patient**
  - Efficient integrated post-approval and follow-up

- **Quantifying the potential substantial benefit**
  - For superior innovation in the field.

- **Increased availability for patients**
  - Evidence vs. access conundrum

**Incorporate a commercialization strategy**

- **Evidence vs. access conundrum**
  - For superior innovation in the field.

- **Increased availability for patients**
  - Evidence vs. access conundrum

**Examples of the levers in action**

- **OMP lifetime/life cycle**
  - 10 years

- **Partner with all key stakeholders**
  - Early and through project

- **Anticipate and plan for clinician and patient unknowns**
  - Provide opportunity to voice concerns and experiences

- **Facilitate communication between all parties involved**

**ADAPT is our commitment to patients, bringing clinical and commercial together for superior innovation in the field.**