

LIVE WEBINAR

# Early Alignment, Enduring Value: Future-Proofing Your TPP

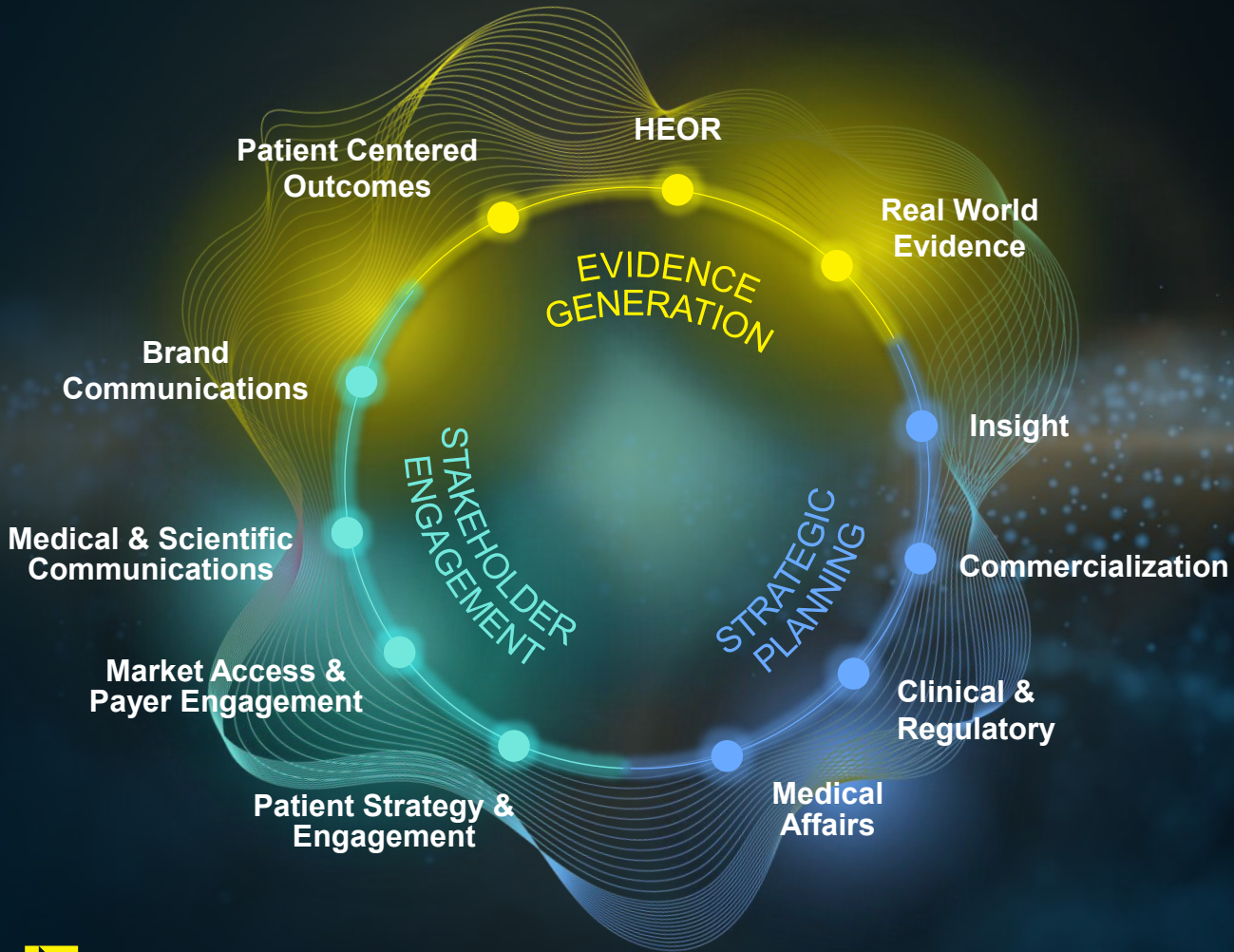


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# Lumanity was designed to engineer *breakthrough value* to tackle our clients' toughest challenges and transform lives



## THE RIGHT CAPABILITIES

We brought together the right collection of industry-leading experts and capabilities to address market complexities and provide end-to-end commercialization support; from initial strategy to market execution.

## INTEGRATED EXPERTISE

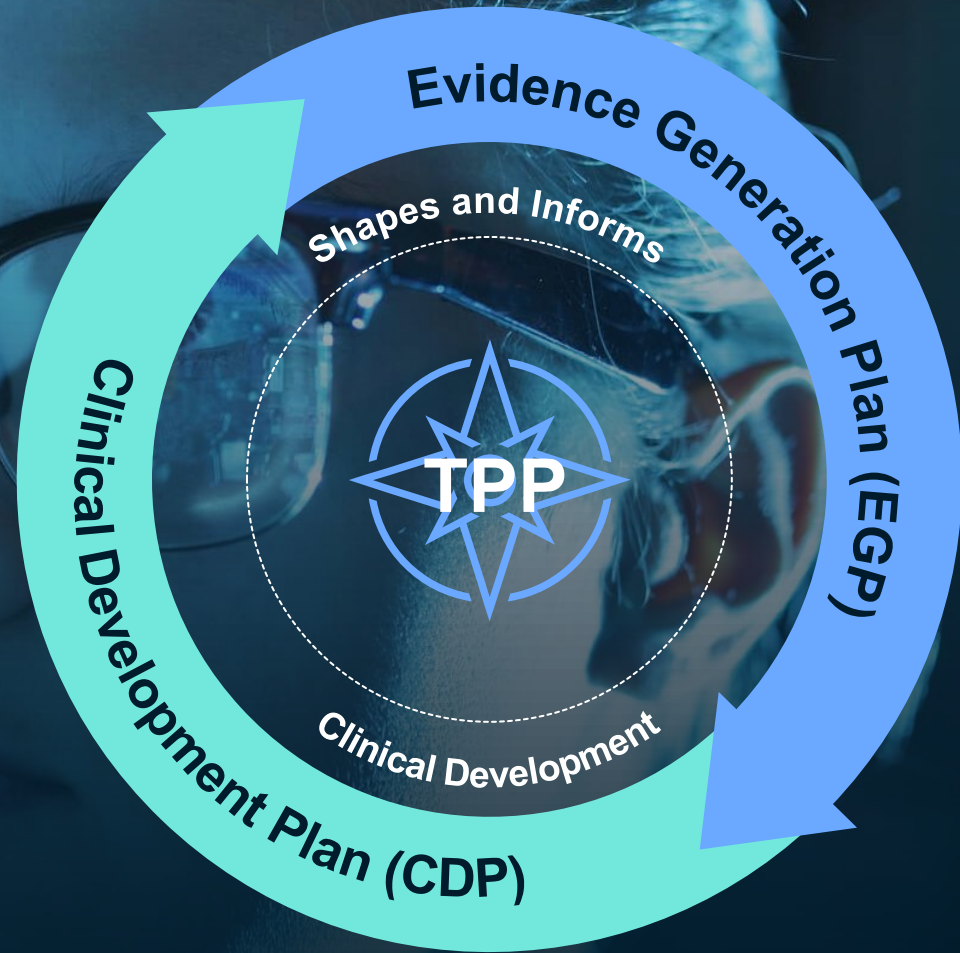
We created an integrated environment that facilitates true collaboration. As one team, we connect the dots so you can move with confidence.

## VALUE-FOCUSED

We are unified by our philosophy around maximizing value throughout the medicine development path. We ensure that every strategic decision contributes to your medicine's success and optimizes patient outcomes.

# Dynamic Blueprint to Guide Development & Commercial Success

Aligning aspirations with real-world forces; early, iteratively, and strategically



# What is a TPP – When done Right?



All-encompassing, multi-dimensional blueprint



Defines the target product vision and evidence requirements for regulatory, commercial, and market access success



Shapes the Clinical Development Plan (CDP) and Evidence Generation Plan (EGP) to align internal and external stakeholders



Starts early (ideally pre-Phase 2a) and evolves continuously

# Common Pitfalls: What Goes Wrong?



TPP created too late  
(Phase 3 “checkbox” exercise)



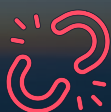
Siloed ownership: Clinical or  
Regulatory only; or Commercial  
functions only



Fails to account for external  
market realities  
(payer hurdles, infrastructure needs,  
advocacy, etc.)



TPPs that mirror the CDP instead of  
shaping the broader EGP → evidence  
gaps and missed opportunities



Stakeholder misalignment:  
Clinical/Regulatory teams drive early  
decisions, but Commercial isn't fully  
engaged until later



Messy “handoffs” as functions change  
lead, causing loss of context and  
momentum

## CASE STUDY

# Reactive TPP Undermines Launch

Client: Large biotech, late-stage oncology asset

### Late TPP

**TPP finalized post-Phase 3, based on CDP decisions.**

Phase 3 endpoints satisfied regulators but didn't address payer concerns (comparative effectiveness, QoL outcomes).

### Reactive Post-launch Evidence

Major EU markets required additional Phase 4 RWE studies for reimbursement.

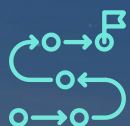
### Consequences

- **Launch delayed 18 months**
- **Peak sales reduced by ~25%**
- **Unplanned \$15M+ in studies**



**Key Lesson:** A future-ready TPP guiding the EGP could have shaped endpoints and evidence to satisfy both regulators and payers.

# Best Practices for Future-ready TPPs



Initiate early and revisit at every milestone



Embed cross-functional and external market lenses



Position the TPP as a strategic driver of the EGP—not a passive reflection of the CDP



Align key stakeholders (Clinical/Regulatory, R&D, HEOR, Market Access, Commercial) from the start



Treat the TPP as a collaborative, living document to streamline transitions between functions



Integrate market forecasting to stress-test assumptions

# What Makes TPP360° Different?

**Envisions a marketed product** (vs development-stage asset) from the beginning

**Elevates the TPP** from passive documentation to an active strategic compass—informing the CDP & EGP and ensuring alignment across Clinical, Regulatory, HEOR, Market Access, and Commercial domains

**Multi-dimensional:** Combines functional and external lenses (patient voice, infrastructure readiness, site of care, education, policy shifts)

**Alignment Engine:** Facilitates collaboration and alignment across all key stakeholders throughout the lifecycle

**Smooths transitions** as the asset moves from R&D-driven to Commercial-driven phases

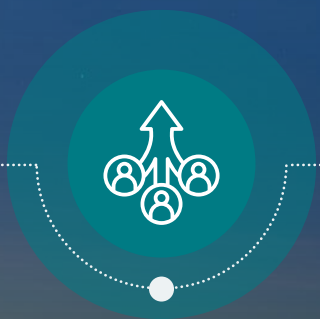
**Value-driven:** Keeps patient, payer, and market value at the center

**Forecast-enabled:** Uses dynamic market forecasts to guide strategic trade-offs

# Our Process Overview



**Early assessment and foundation building**



**Cross-functional workshops to achieve alignment**



**Early market input**  
(e.g., KOL, physician, patient interviews)



**Iteratively update the TPP to guide the EGP and avoid downstream rework**



**Continuous adaptation as data emerges and markets evolve**

## CASE STUDY

# TPP360° Drives Access & Launch Speed

Client: Mid-sized pharma, novel neurology therapy

Engagement: Initiated pre-Phase 2a with Lumanity

### TPP360° Compass Guiding EGP Components

- Future-ready TPP shaped a cohesive EGP—clinical endpoints, HEOR strategies, payer-focused value messaging
- Early workshops aligned R&D, Commercial, and Access teams
- External lenses anticipated payer and site-of-care challenges

### Key Metrics

- Phase 3 designed with meaningful endpoints for regulators *and* payers
- Early payer briefings in EU markets streamlined value dossier development
- Upon launch, achieved unconditional reimbursement in 7 major EU markets within 3 months
- Exceeded uptake forecasts by 30%



**Key Lesson:** TPP360° transformed the TPP into a living strategic compass – driving evidence generation and aligning stakeholders early for market success.

# Questions on TPP360°





# TPP360° can help your teams future-proof your assets

*Start early. Think dynamically. Align your teams around a TPP that's more than a document—it's a strategic compass guiding a cohesive Evidence Generation Plan.*

Contact us to start the conversation! Email [contact@lumanity.com](mailto:contact@lumanity.com)