



# The Preferences for Advanced Therapy Medicinal Products: A Multi-criteria Decision Analysis Framework

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## Introduction

Advanced therapy medicinal products (ATMPs)—including gene therapies, somatic cell therapies, and tissue-engineered medicines—represent revolutionary treatments for previously untreatable or inadequately managed conditions.

However, ATMPs present unprecedented challenges for healthcare systems due to their exceptional costs, limited long-term efficacy data, complex manufacturing requirements, and uncertain durability of effect.

**The study aims to deliver an ATMP-specific MCDA framework that balances affordability, clinical effectiveness, and long-term value considerations.**

## Methods

**Mixed-methods approach in four phases:**

### Phase 1: Literature Review

Systematic review of MCDA frameworks (EVIDEM, Advanced Value Framework, Hungary's National Framework, VALIDATE) and HTA decisions for approved ATMPs to identify evaluation patterns and applicability to ATMPs.

### Phase 2: Criteria Development

Two-round modified Delphi survey with multidisciplinary expert panel (n=25: clinicians, health economists, patient representatives, payers, industry specialists, bioethicists) to refine a comprehensive criteria list.

### Phase 3: Weight Elicitation

The Analytic Hierarchy Process (AHP) was applied to establish stakeholder preferences and determine final criterion weights.

## Results

Table 1: Demographics characteristics of experts.

	N=25	%
<b>Gender</b>		
Female	15	60%
Male	10	40%
<b>Age</b>		
41-50 years	6	24%
51-60 years	8	32%
61-70 years	9	36%
Above 71 years	2	8%
<b>Stakeholders</b>		
Government authorities	2	8%
Patient organizations	5	20%
Academic/clinical experts	11	44%
Healthcare providers	4	16%
Industry specialists and bioethicists	3	12%

Table 2: Rank of the Criteria

Domains/Criteria	Ranking
Improvement of Efficacy/ Effectiveness	1
Unmet Medical Needs	2
Improvement of Adverse events and Tolerability	3
Evidence on Efficacy and Comparative Effectiveness	4
Disease Severity	5
Size and Design of Trials	6
Disease Progression and Long-Term Effects	7
Public Health Interest	8
Affordability	9
Ethical analysis	10
Cost-effectiveness	11
Innovation	12
Family and Societal Impact	13
Equity	14
Budget Impact	15
Generalizability	16
Patient-reported Outcomes	17
Value of Hope	18

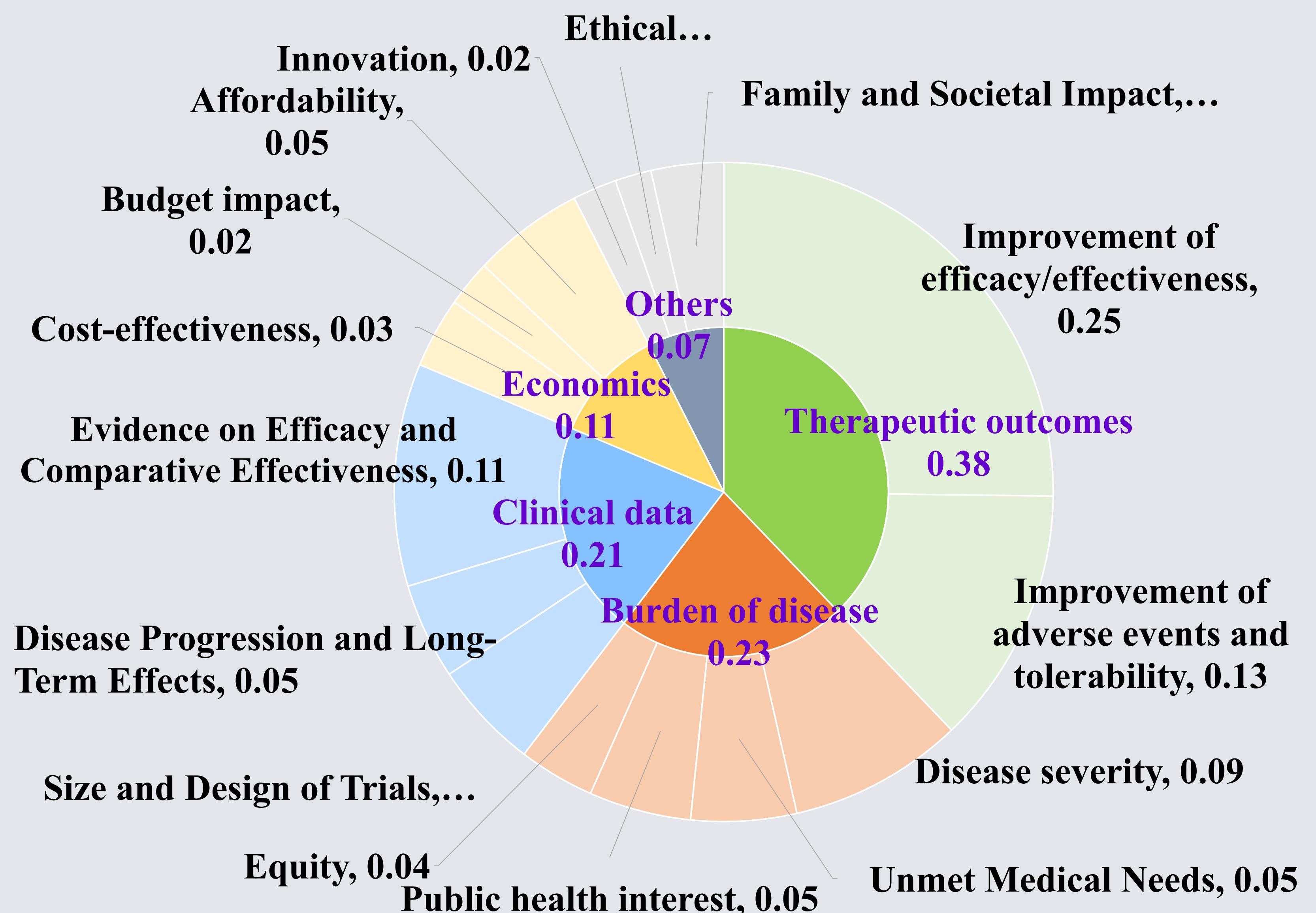


Figure 1. Criteria weights of the professionals

■ Burden of disease ■ Therapeutic outcomes ■ Economics ■ Clinical data ■ Others

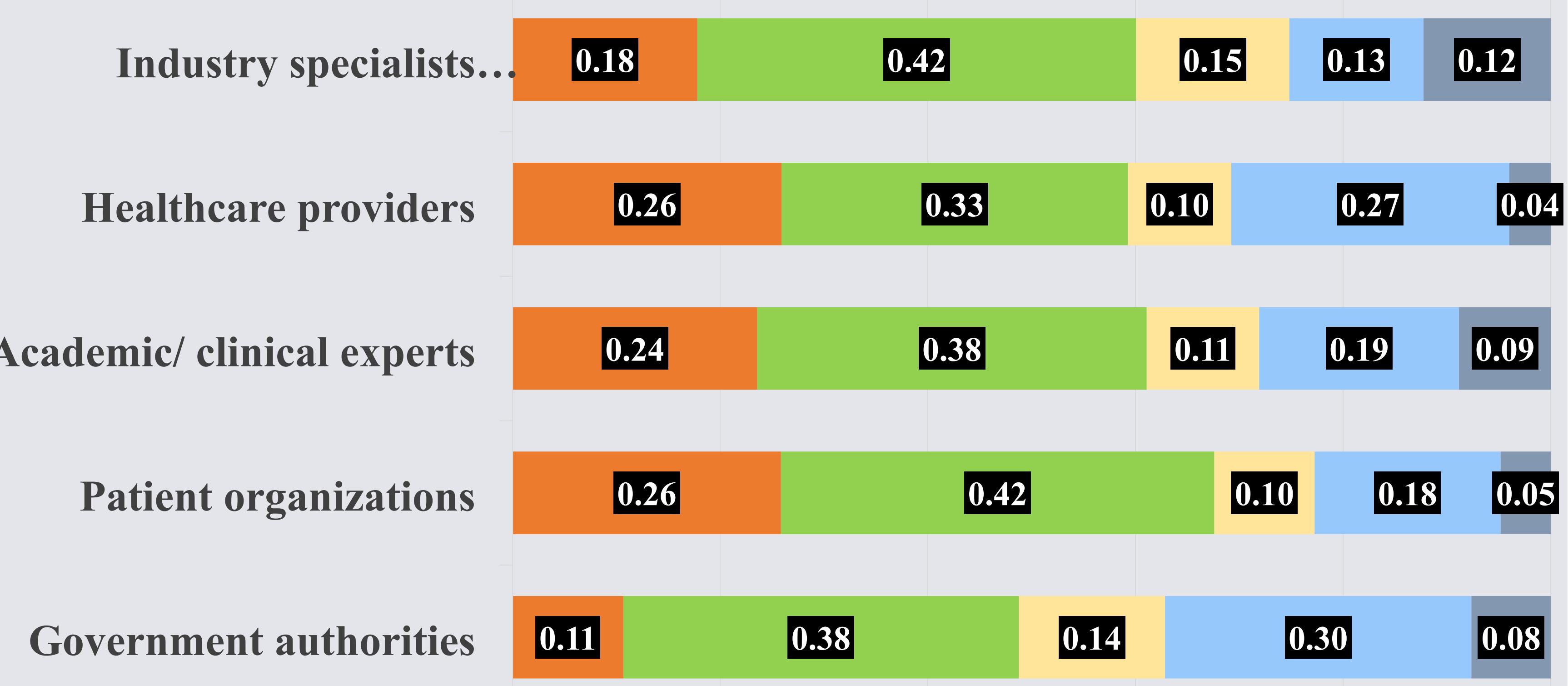


Figure 2. Domain weights for different stakeholders

## Conclusions

AHP was applied to establish stakeholder preferences for the refined framework. We expect this framework to provide decision-makers with a structured approach to evaluate ATMPs.