



# 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% |

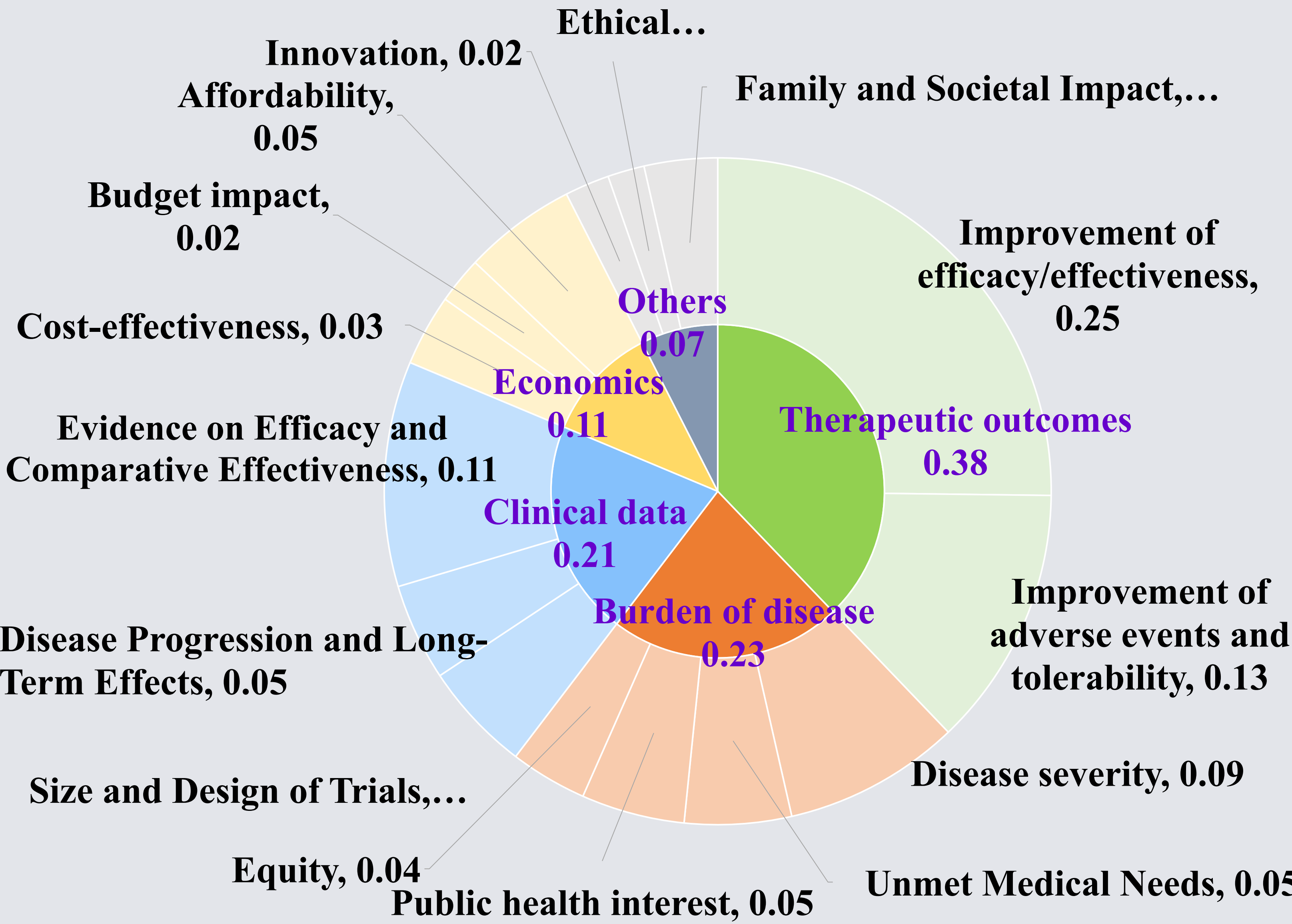


Figure 1. Criteria weights of the professionals

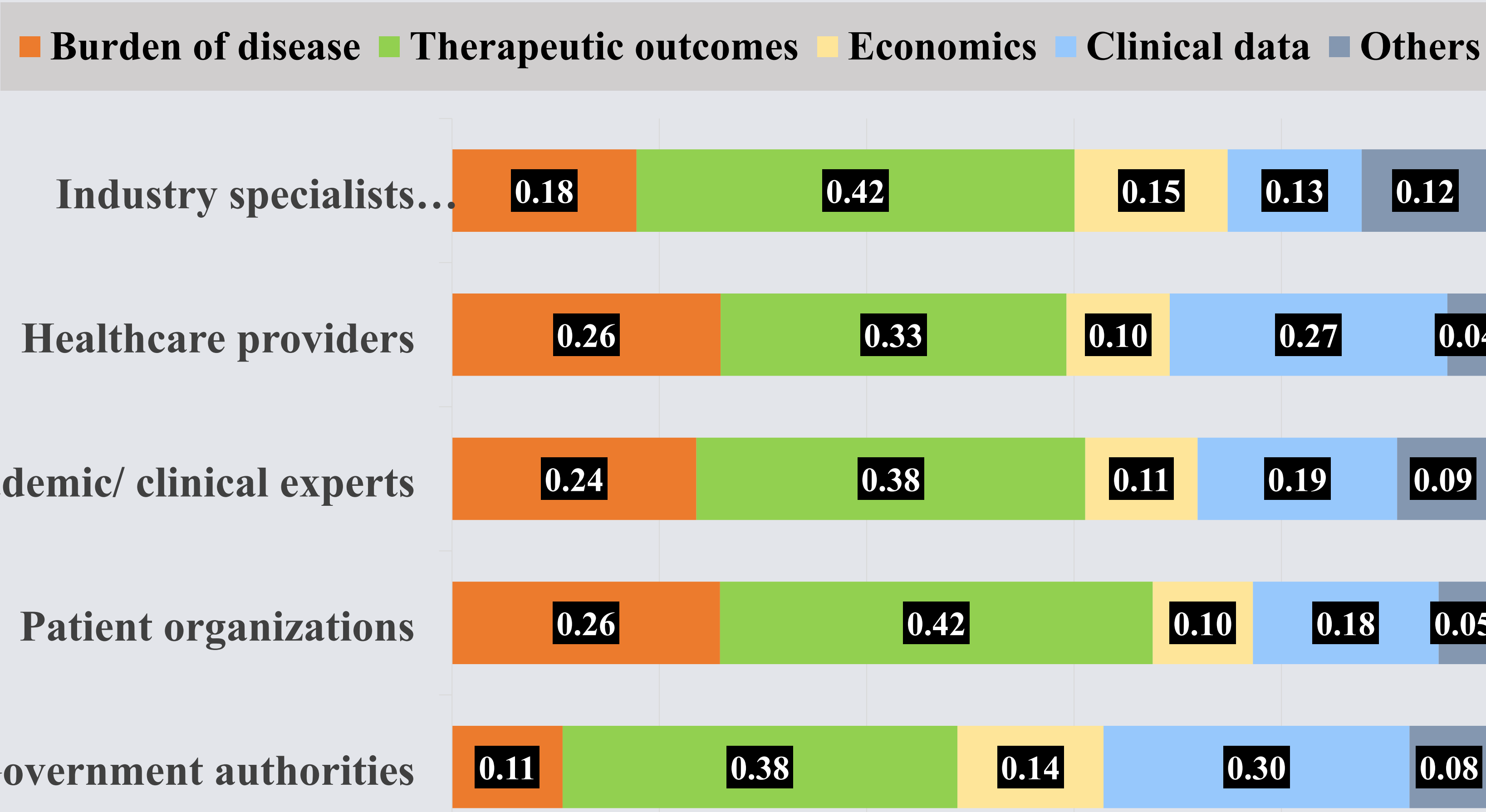


Figure 2. Domain weights for different stakeholders

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      |

## 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.