

Emerging Trends in the Adoption of Alternative Financing Models for Advanced Therapy Medicinal Products: A Scoping Review

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Introduction

- Advanced therapy medicinal products (ATMPs), such as somatic-cell and gene therapies, pose unique market challenges due to their high costs, which can range from hundreds of thousands to millions of Euros per treatment; Thus, funding decisions for these therapies are significant, even for very rare diseases.^[1]
- In response to the increasing pressure placed on health system budgets, both payers and manufacturers are increasingly exploring insurance solutions to ensure affordability and sustainability of the ATMP market.^[2-4]
- Warranty policies compensate payers if a therapy underperforms, with third-party insurers bearing the costs; whereas, on the payer side, strategies such as risk pooling and reinsurance may be used to mitigate financial liabilities associated with ATMP coverage.^[2-4]
- Alternative financing models (AFMs) for high-cost ATMPs, such as third-party warranty, risk-pooling and reinsurance aim to reduce budget uncertainty in the sale and coverage of high-cost therapies; However, their impact on patient access remains uncertain.^[2-4]
- This study aimed to identify emerging trends in AFMs for ATMPs and characterise the factors associated with their use.

Methods

- A comprehensive scoping review of the literature published between Jan 2019 – May 2024 was conducted.
- Literature sources included bibliographic databases indexing peer-reviewed journals of both biomedical and social sciences (Medline, Embase, Global Health, Health Management Information Consortium and the Cochrane Library) and grey literature.
- Grey literature searches centred on the websites of industry and payer organisations, and relevant authorities responsible for the regulation of pharmaceutical products, management of pharmaceutical budgets or the appraisal of health technologies, in anticipation of published policy statements or information on ATMP funding decisions.
- Publications were included in the review if they discussed AFMs in the context of ATMPs (or related factors) in Global markets.
- Verbatim extracts from relevant discussions of AFMs were captured using a standardized charting form and subsequently free-form coded by a single reviewer.
- Coded data were analysed for descriptive and overarching analytic themes representative of concepts describing the AMFs landscape using the methods described by Thomas and Harden (2008).^[5]
- A narrative synthesis was undertaken, which consisted of a descriptive summary of the coded information extracted from all publications and an exploration of the associations between prominent themes.

Results

- Bibliographic database searches returned 127 records and after removing duplicates, 126 publications remained for title and abstract screening; Of these publications, 34 were passed for full-text assessment, of which 23 were selected for inclusion in the review.
- Grey literature searches returned 12 records, of which 11 were selected, giving a total of 34 articles included in the review; A combined PRISMA flow diagram is shown in **Figure 1**.
- Of the 34 publications, 24% had a Pan-European focus, 18% adopted a global perspective, and 34% focused on the US. Publications referencing individual European markets contributed 6% for the UK, and 3% each for Germany, Italy, France, Switzerland, the Netherlands, and Russia.
- Content analysis of the reviewed publications identified 10 descriptive themes, capturing diverse factors such as AFM applications, health system structures, and market dynamics (**Figure 2**).
- Descriptive themes were consolidated into eight broader analytical categories, highlighting both barriers and opportunities for increasing the use of AFMs; Key themes included the suitability and sustainability of innovative payment models, risk and uncertainty management, long-term clinical and economic viability, and regulatory challenges.
- The most frequently described AFMs were third-party warranties, risk-pooling, and reinsurance for high-cost therapies like ATMPs; Notable issues in their adoption are described in **Table 1**.
- A hypothetical model of relationships between analytical themes, based on prominence in the literature, is presented in **Figure 3**.

Table 1. Barriers to the adoption of alternative financing models.

Alternative financing model	Barrier(s) to adoption
Third-party warranty	<ul style="list-style-type: none">Challenges in defining success criteria for therapies with uncertain long-term outcomes.<ul style="list-style-type: none">How long should the therapy work to be considered successful?What side effects or complications might negate the warranty?
Risk-pool	<ul style="list-style-type: none">If the pool is too small, it may not absorb high costs effectively, and if too large, some contributors may feel they are paying more than their fair share.Since ATMPs can be prohibitively expensive, the pool may need frequent “replenishment”.For payers with limited financial resources, there may be concerns about the long-term sustainability of risk-pooling mechanisms, particularly if the number of patients requiring high-cost therapies continues to grow.
Re-insurance	<ul style="list-style-type: none">Difficulties in pricing premiums due to limited long-term outcome data.Transferring the financial risk may face regulatory scrutiny - In some regions, regulatory frameworks may not be well-adapted to address the unique risks posed by ATMPs, requiring additional compliance efforts or legal modifications.

Figure 1. PRISMA flow diagram.

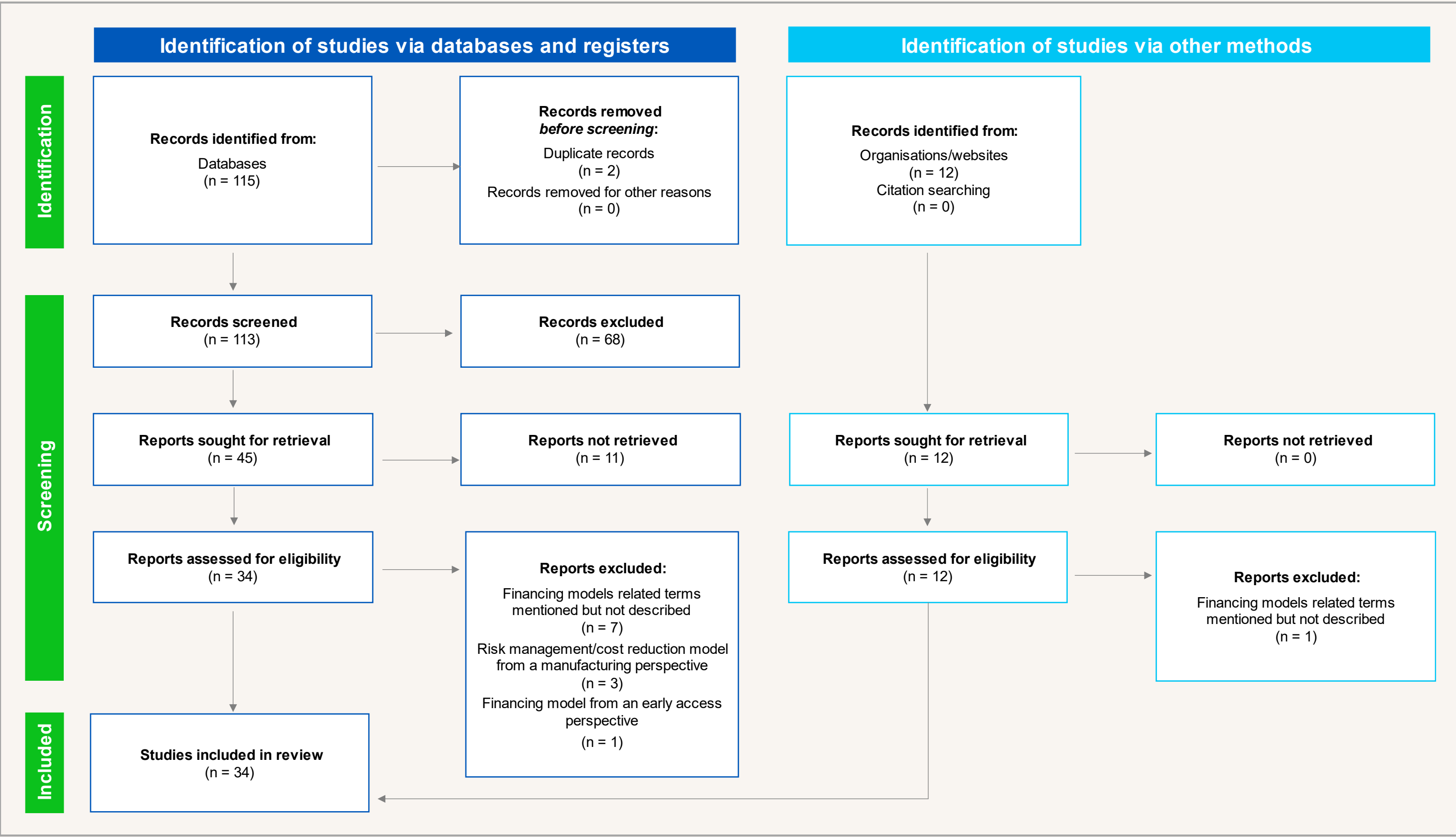
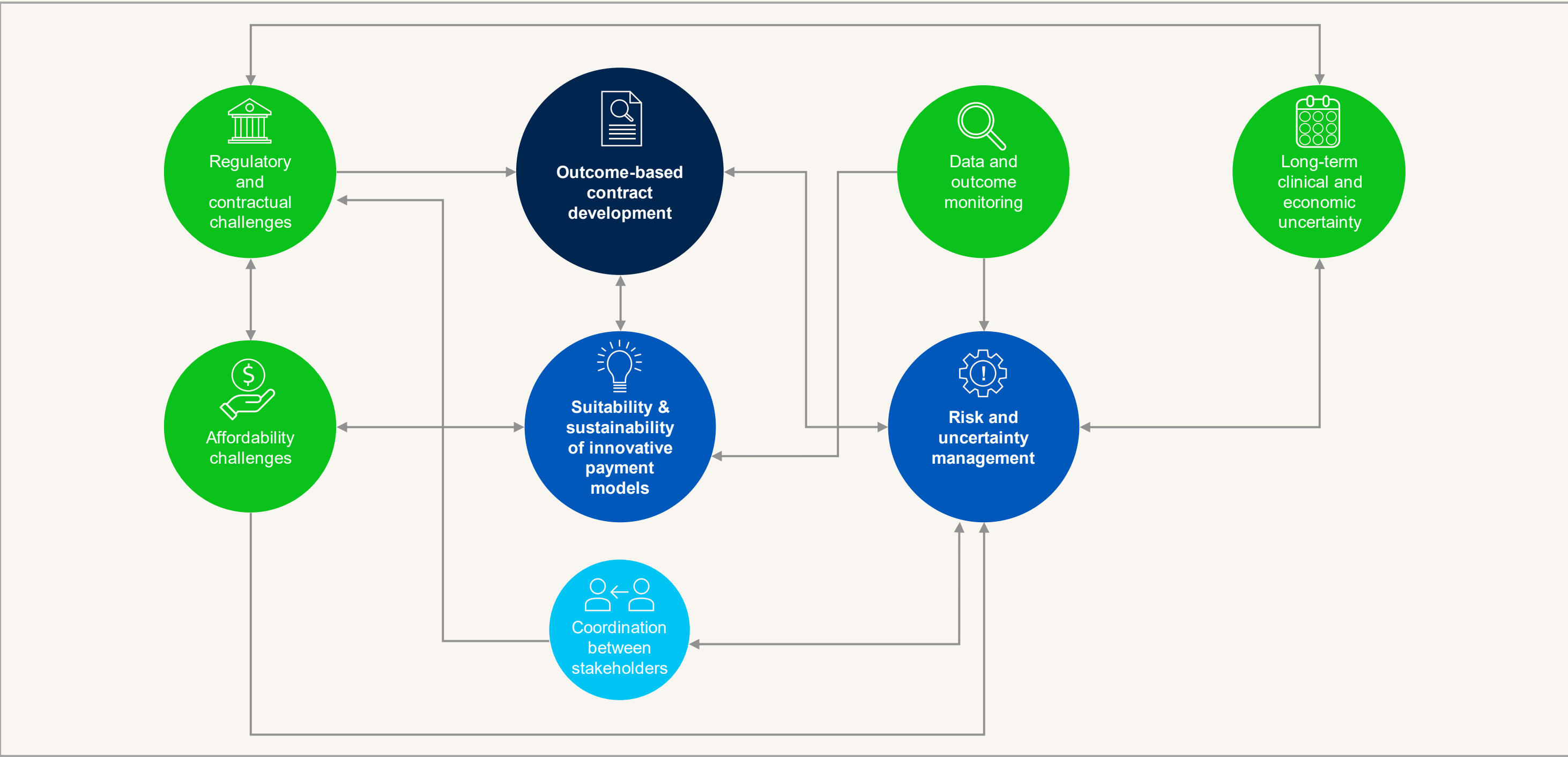


Figure 2. Factors associated with AFMs of ATMPs by frequency in the literature.



Figure 3. Hypothetical model of thematic relationships. Single and double arrows represent unidirectional and bidirectional relationships, respectively. Circle size is indicative of relative significance, based on prominence in the literature



Conclusions

- Despite the complexities involved, AFMs for high-investment therapies such as ATMPs are likely to become more prevalent as an increasing number of products reach the market and payers struggle to match healthcare demands.
- These complexities underline the need for innovative solutions and frameworks that allow AFMs to evolve in a sustainable and efficient way while balancing the needs of patients, payers, and manufacturers.
- Future research should aim to assess the impact of AFMs on patient access to ATMPs.

Abbreviations

AFM = alternative financing model; ATMP = advanced therapy medicinal product; UK = United Kingdom; US = United States.

References

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