

EVOLUTION OF CLINICAL TRIALS WITH ADVANCED THERAPY MEDICINAL PRODUCTS AT A TERTIARY CARE CENTER: EXPERIENCE 2022-2025

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Background and importance

Advanced Therapy Medicinal Products (ATMPs) are innovative medicines classified into three categories:

- Gene therapy**: uses recombinant genes created in the laboratory to treat, prevent or diagnose diseases.
- Somatic-cell therapy**: contains manipulated cells or tissues with altered characteristics or new functions.
- Tissue-engineered**: use modified cells or tissues to repair, regenerate or replace human tissue.

Aim and objectives

To evaluate the growth and identify emerging trends in the development of ATMPs at our hospital during the last few years.

Materials and methods

Observational, descriptive, and retrospective study with a comparative analysis of the evolution of CT in ATMPs at a tertiary care hospital between 2022-2025. The variables analysed included the number of CT of ATMPs, type of ATMPs (gene therapy, somatic-cell therapy or tissue-engineered), number of patients per trial and per therapy type during the specified period.

Results

We participated in **38 CT** with ATMPs:
 28 were conducted between 2022-2025:

- 46.5% Gene therapy:
 - 53.8% RNAm
 - 38.5% viral vectors
 - 7.7% others
- 53.5% Somatic-cell therapy:
 - 60.0% CAR-T
 - 13.3% Tumor-Infiltrating lymphocytes (TIL)
 - 13.3% Mesenchymal Stromal Cells (MSC)
 - 6.7% Lymphocyte T-citotoxic (LTC)
 - 6.7% Autologous Engineered Macrophages
- Any CT involving tissue-engineered.



We treated **55 patients** with ATMPs (2022-2025):

- 54.5% Gene therapy:
 - 53.8% RNAm
 - 38.5% viral vectors
 - 7.7% others
- 45.5% Somatic-cell therapy:
 - 63.6% CAR-T
 - 4.5% TIL
 - 22.7% MSC
 - 4.5% LTC
 - 4.5% AEM

	2022	2023	2024	2025	TOTAL
ARNm	1	1	4	1	7
Viral vectors	0	4	1	0	5
Other gene-therapy	0	0	0	1	1
CAR-T	0	2	3	4	9
MSC	0	1	0	1	2
TILs	0	0	0	2	2
LTC	1	0	0	0	1
AEM	0	0	0	1	1
TOTAL	2	8	8	10	28

Table 1. CT with ATMPs between 2022 and 2025

	2022	2023	2024	2025	TOTAL
ARNm	0	2	10	9	21
Viral vectors	0	0	8	0	8
Other gene-therapy	0	0	0	1	1
CAR-T	0	0	6	8	14
MSC	2	2	1	0	5
TILs	0	0	0	1	1
LTC	1	2	1	0	4
AEM	0	0	0	1	1
TOTAL	3	4	8	20	55

Table 2. Patients included in CT with ATMPs between 2022-2025.

Conclusion and relevance

A substantial increase was observed in both the number of CT and patients treated with ATMPs. mRNA and CAR-T therapies showed the most pronounced growth starting from 2024. In contrast, viral vectors, MSC, and LTC exhibited declining trends. Notably, in 2025, the center engaged in an increasing number of novel therapies, including TILs and AEMs, reflecting diversification and consolidation of expertise across advanced therapeutic modalities. The slight decline in 2025 is likely due to the pending completion of the final quarter.

