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Classification and assessment of the complexity of onco-haematology clinical trials from a pharmacy service perspective

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BACKGROUND AND IMPORTANCE

Clinical trials (CTs) in **onco-haematology** are a breakthrough in cancer treatment but require meticulous management by the **pharmacy** service (PS) due to their complexity. Assessing the **complexity** of these trials helps to efficiently allocate resources and **optimise** the pharmacy workflow.

AIM AND OBJECTIVES

To classify onco-haematological CTs and to **assess their complexity** from the point of view of the PS.

MATERIAL AND METHODS

A retrospective observational descriptive study of onco-hematological CTs initiated in 2023.

The following characteristics were analyzed/collected for each CT: research phase and pathology treated.

- **Complexity** was assessed using the Calvin et al. complexity scale, considering aspects like blinding, number of drugs, PS professionals involved, dispensing method, IT system usage, dosing, storage conditions, and need for special packaging.
- CT complexity was categorized as **low** (6-10 points), **moderate** (11-19 points), and **high** (20-33 points).

Overall complexity was calculated by pathology and phase. Fundanet® was used for data extraction and Excel® for data analysis.

RESULTS

In 2023, **84 CTs were initiated**, 58 (69%) in oncology and 26 (31%) in hematology.

Phase I: 25 CTs (30%)

Phase II: 30 CTs (36%)

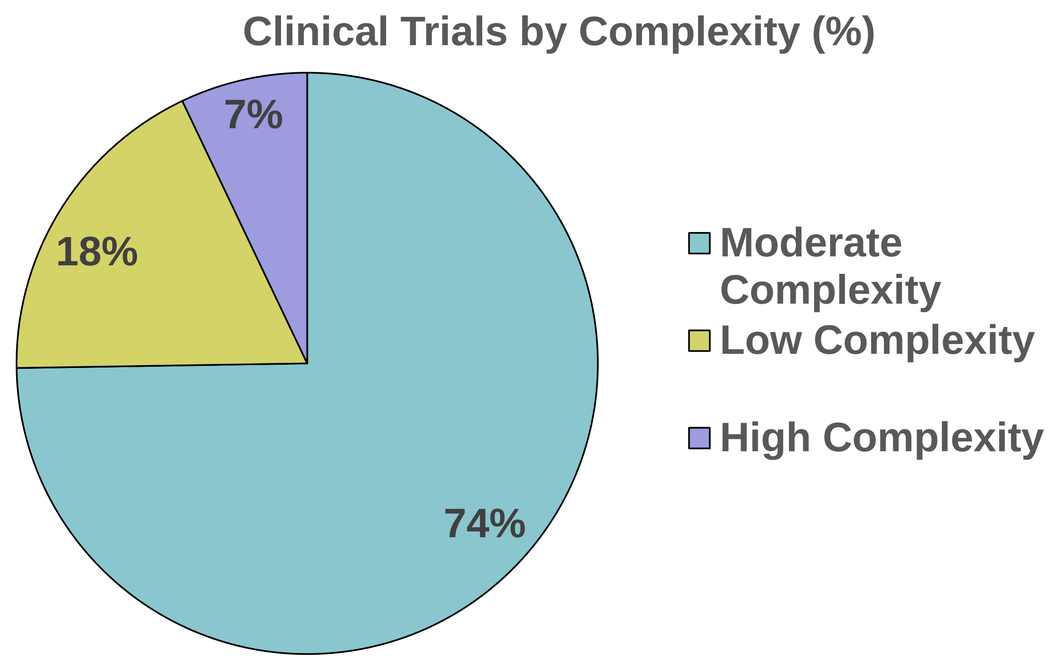
Phase III: 27 CTs (32%)

Phase IV: 2 CTs (2%)

The pathologies with the most CTs:

In **oncology**: lung 16 (28%) and breast 12 (22%).

In **hematology**: lymphomas 7 (28%), leukemias 6 (23%).



The aspects that **most increased complexity** were: number of drugs involved, dispensing method, and storage conditions.

Of the 7 highly complex CTs**, acute myeloid leukemia and lung cancer** were the most frequent pathologies, 29% in both cases. Most highly complex trials were **phase I** (57%).

CONCLUSION AND RELEVANCE

- **36% of analyzed CTs included phase II drugs. The most studied pathologies were lung cancer, breast cancer, lymphomas, and leukemias.**
- **74% of the CTs had a moderate overall complexity. AML and lung cancer were the most complex pathologies, and phase I trials scored the highest on the Calvin et al. scale.**
- **The inclusion of parameters such as the number of modifications of pharmaceutical procedures and treatment schedules could further increase the understanding of complexity.**
- **Performing such evaluations allows us to understand the complexity of CTs and allocate resources more efficiently.**

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