HIV Exclusion Without Justification in Non-HIV Clinical Trials: A Five-Therapeutic-Area Analysis

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Background

People living with HIV face elevated risk for multiple non-HIV conditions yet often remain systematically excluded from trials evaluating therapies for these conditions. Exclusion from oncology and cardiovascular trials has been described previously, but cross-therapeutic-area quantification is absent, and the operational mechanism driving persistent exclusion remains undefined.

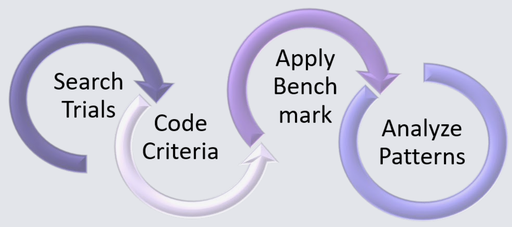
Improved HIV care outcomes and life expectancy have resulted in a growing population whose eligibility is governed by legacy protocol language.

Hypothesis: HIV exclusion correlates with absence of structured drug–drug interaction (DDI) and immunosuppression-related decision frameworks rather than clinical necessity.

Methods

Cross-sectional analysis of Phase 2/3 non-HIV trials on ClinicalTrials.gov (April 2026).

1. **5 areas**: cardiovascular, oncology, metabolic, neurology, IMID
2. **Coded:**
   - Categorical HIV exclusion (blanket exclusion without clinical threshold)
   - Immunocompromised sweep Language (broad exclusion without specifying HIV)
   - Parameter-based inclusion (eligibility conditional on CD4, viral load, or ART stability)
   - Documented DDI rationale
3. **Benchmarked** vs. SGMA HIV Inclusion Protocol Standard (SGMA-STD-HIV-001)



Results

Key Results

- ❖ Of 335 trials analyzed, 142 (42.4%) contained HIV-related exclusion criteria
- ❖ Most exclusion occurs through broad, non-HIV-specific sweep language rather than named HIV criteria (Table 1)
- ❖ Hypothesis Preliminarily Supported: Clinical necessity and DDI do not appear to correlate with HIV exclusion

Exclusion by Therapeutic Area

Percent of trials with HIV-related exclusion criteria, by therapeutic area:

- ❖ Oncology: **59.1%**
- ❖ IMID: **42.3%**
- ❖ Metabolic: **32.4%**
- ❖ Neurology: **29.6%**
- ❖ Cardiovascular: **14.6%**

Cross-therapeutic-area variation did not track pharmacologic risk

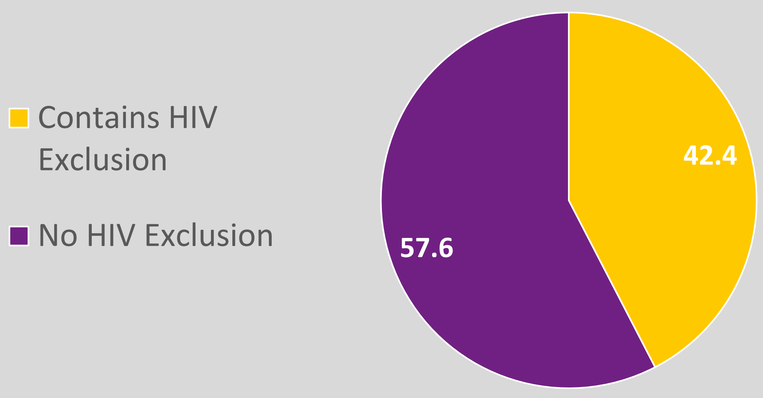


Figure 1. Proportion of trials analyzed containing HIV-related exclusion criteria

Eligibility Metric	Result
Trials analyzed (N)	N = 335
Any HIV-related exclusion	42.4%
Categorical exclusion (blanket)	9.0%
Immunocompromised sweep language	33.4%
Parameter-based inclusion	7.8%
DDI rationale provided*	24.6%

Table 1. Categorization of eligibility metrics excluding people with HIV found in clinical trial protocols posted on ClinicalTrials.gov

Conclusions

Exclusion of people with HIV from non-HIV clinical trials is not supported by consistent pharmacologic justification: ~75% of excluding trials provide no interaction rationale. The majority of exclusion occurs via sweeping non-HIV specific criteria, which may be missed by conventional analyses.

Parameter-based eligibility grounded in structured DDI and immunological assessment offers a scalable mechanism to transform categorical exclusion into evidence-based inclusion. SGMA-GOV-HIV-CV-001 specifies this adjudication for cardiovascular agents.

Modernizing clinical trial eligibility criteria could protect trial integrity while ending the exclusion of people with HIV from trials evaluating conditions that affect them disproportionately.

Implications

- Cross-sectional design captures eligibility language at a single time point; actual enrollment practices may differ.
- Findings support parameter-based eligibility as a scalable, evidence-based alternative to categorical HIV exclusion.

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***Conflict of interest**: Garo Kiledjian is Founder and CEO of SGMA. SGMA-STD-HIV-001 is cited in Methods as the evaluative benchmark; no commercial interests are associated with its use.* ***Contact**: kemi.williams@gmail.com; info@sgma.global*