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DESIGN CHARACTERISTICS AND ENROLLMENT OF COMPLETED AI DESIGNED SMALL MOLECULE CLINICAL TRIALS GLOBALLY

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Abstract:

This analysis examines how recorded trial design and actual enrollment differ across AI designed small molecule medicines, addressing the interpretation of clinical development evidence across settings. Public ClinicalTrials.gov records provide a cross section of two completed phase 1 trials conducted in the United Kingdom and New Zealand within an eligibility window covering 2010 to 2022. Descriptive summaries and direct comparisons preserve allocation, masking, and registered arm count as distinct characteristics. Both trials report randomized allocation, but the trial with two registered arms enrolled 78 participants compared with 64 in the trial with three arms, a difference of 21.88%. The latter trial's overall masking designation also encompasses different procedures across its parts. These observations distinguish intervention structure from participant volume and show why summary categories require procedural context. The contribution is a traceable comparison demonstrating that registered arm count and enrollment have different orderings within the selected cases. For international registry users, the findings support comparing complete trial configurations and retaining procedural qualifications when assessing clinical development activity.

Key Words: Artificial Intelligence; Drug Development; Clinical Trial Design; Trial Enrollment; Descriptive Analysis

1. Introduction:

Interpreting the clinical development of AI designed medicines requires a clear distinction between how trials are organized and how many participants they enroll. Allocation, masking, and registered arm count describe different features of trial design, while actual enrollment records participant volume. Treating these measures as interchangeable can obscure the clinical evidence associated with a candidate medicine. Vamathevan et al., 2019, describe the applications of machine learning across drug discovery and development, while Bender and Cortés Ciriano, 2021, emphasize the distinction between computational achievements and their relevance to drug development. These perspectives establish the need for precise empirical descriptions of the clinical trials through which AI designed candidates enter human evaluation.

Public trial registries provide a basis for examining this distinction. ClinicalTrials.gov records trial identifiers, intervention structures, allocation procedures, masking designations, and enrollment information within a shared reporting system. Zarin et al., 2011, explain how this infrastructure makes clinical research information accessible for examination. However, the availability of standardized fields does not make their meanings equivalent. An enrollment target differs from actual participation, an overall masking category may summarize several procedures, and registered arms describe intervention conditions rather than every dose cohort. Interpretation therefore depends on preserving the definition and level of aggregation of each field.

Experimental design provides the conceptual foundation for examining these measures together. Allocation organizes participant assignment to intervention conditions. Masking controls access to information about that assignment. Registered arms identify the listed intervention structure, while enrollment measures the participants recorded across the trial. These dimensions contribute to different aspects of evidence generation. Hróbjartsson et al., 2012, demonstrate that knowledge of treatment assignment can influence outcome assessment, establishing the relevance of masking procedures to interpretation. Their evidence does not imply that masking categories determine enrollment; it explains why masking must retain its procedural meaning when compared with participant counts.

The relationship between intervention structure and participant volume also requires careful specification. Additional registered arms create more listed intervention conditions, but total enrollment depends on how the protocol distributes participants across those conditions. Chan et al., 2013, distinguish trial structure, intervention procedures, and sample size justification within protocol documentation. Getz and Campo, 2018, further show that protocol complexity encompasses procedures, visits, and investigative workload. Together, these contributions establish that arm count captures a specific structural feature rather than a comprehensive measure of clinical activity. They provide a rationale for examining arm count alongside enrollment while keeping both measures separate.

The closest literature therefore addresses complementary questions: computational reviews examine the contribution of artificial intelligence to discovery, protocol research characterizes trial organization, and

registry research examines the accessibility and interpretation of recorded information. The present analysis brings these perspectives together through a descriptive comparison of two completed AI designed small molecule trials. Its contribution concerns the interpretation of observed trial configurations. It connects allocation, masking, and registered arm count with actual enrollment in identifiable records, preserving distinctions that can disappear when clinical development is summarized through a single indicator.

This study aims to characterize the recorded design configurations and actual enrollment of two completed phase 1 trials involving EXS21546 and INS018_055. Eligibility covered trials started and completed from 2010 to 2022. The retained records concern trials conducted in the United Kingdom and New Zealand and form a cross section with one observation per trial. The analysis uses ClinicalTrials.gov identifiers NCT04727138 and NCT05154240, retains the original design categories, and compares actual participant counts through descriptive summaries. It asks which allocation methods, masking categories, and registered arm counts characterize the selected trials, and how actual enrollment differs across their recorded configurations.

The findings identify shared randomized allocation alongside differences in masking, arm count, and enrollment. The trial with fewer registered arms records greater actual enrollment, while the overall masking designation of the other trial encompasses different procedures across its parts. These observations provide a concrete contribution to interpreting registry information: intervention structure and participant volume have different orderings within the selected cases, and an overall design category requires its accompanying procedural context. The relevance extends to analysts and reviewers comparing trials across settings through common registry fields. The evidence supports a transparent comparison of these two records, with each conclusion tied to the measure that establishes it.

2. Theory, Conceptual Framework and Research Questions Development:

Clinical trials connect molecular discovery with structured observation in humans. Within this system, sponsors specify treatment conditions, investigators implement protocols, and participants contribute observations under defined procedures. Experimental design provides the theoretical foundation for understanding how these relationships organize evidence generation. Artificial intelligence contributes upstream by supporting molecular identification and optimization. Vamathevan et al., 2019, describe these applications across drug discovery and development, providing the technological context for examining the subsequent organization of clinical trials.

This analysis examines trial design and actual enrollment as distinct, observable features of two completed clinical trials involving AI designed small molecule medicines. Trial design comprises allocation, masking, and the number of registered arms. Actual enrollment denotes the recorded number of participants enrolled in each trial. Paul et al., 2021, situate artificial intelligence within an interdependent pharmaceutical development process. This perspective supports examining the clinical arrangements through which computationally developed candidates enter human evaluation, while keeping molecular design and trial organization conceptually distinct.

Allocation defines how participants enter intervention conditions. Its theoretical function concerns the comparability of groups and the organization of treatment assignment. Random allocation reduces systematic differences arising from assignment decisions, although its implementation remains distinct from the number of participants ultimately enrolled. Schulz et al., 2010, identify allocation procedures and participant flow as separate reporting requirements. Accordingly, this analysis describes the recorded allocation method for each trial and considers enrollment alongside that method without assigning a directional relationship between them.

Masking governs access to information about treatment assignment. Its mechanism concerns how knowledge of assignment can influence participant responses, clinical decisions, and outcome assessment. Hróbjartsson et al., 2012, provide empirical evidence that unmasked assessment can distort estimated intervention effects. That finding establishes the relevance of masking to evidence generation. Here, masking is represented by the categorical registry designation, with attention to differences between the overall designation and the procedures described for individual trial parts. The comparison therefore retains the meaning of the recorded categories rather than treating them as a numerical quality scale.

The number of registered arms represents the organizational structure of the intervention conditions. An additional arm introduces another registered condition, but its implications for total enrollment depend on how participants are distributed across the protocol. A larger arm count can accompany a larger participant requirement, while different allocations across conditions can produce another pattern. These possibilities provide competing theoretical expectations rather than an established relationship. Chan et al., 2013, distinguish trial structure, intervention procedures, and sample size justification within protocol reporting. This analysis therefore counts registered arm entries separately from actual enrollment and preserves the distinction between an arm and a dose cohort.

The conceptual framework organizes allocation, masking, and registered arm count as observed design characteristics considered alongside actual enrollment. Each characteristic retains its original measurement: allocation and masking remain categorical, arm count remains a count, and enrollment remains the number of

participants. The framework guides a descriptive comparison of the two trial configurations. We examine the recorded characteristics individually and then compare the enrollment accompanying each configuration.

RQ1: What allocation methods, masking categories, and numbers of registered arms characterize the two selected completed clinical trials?

RQ2: How does actual enrollment differ between the two trials when considered alongside their recorded design characteristics?

3. Data:

This analysis uses verified trial records to document data provenance, define the comparison sample, and operationalize trial design and enrollment.The resulting dataset supports a descriptive comparison of two completed clinical trials through consistent identifiers, recorded design characteristics, and actual participant counts.

3.1 Data Sources, Population, and Sample Construction:

The analytical dataset contains public registration records from ClinicalTrials.gov, maintained by the United States National Library of Medicine. Records were accessed through the version 2 application programming interface and linked to their public study pages. The stable identifiers are NCT04727138 for EXS21546 and NCT05154240 for INS018_055. The supplied workbook preserves trial dates, record update dates, extraction timing, source URLs, and supporting evidence of AI involvement separately. These records contain aggregate trial information rather than individual participant data. Zarin et al., 2011, describe the registry structure and its role in making clinical research information accessible.

The target population comprises completed human interventional trials of AI designed small molecule medicines within the eligibility window documented in the workbook. The accessible sample comprises two verified phase 1 trials, one conducted in the United Kingdom and one in New Zealand. Selection required an identifiable registry record, documented AI design attribution, completed status, actual enrollment, and actual completion within the specified window. The dataset forms a cross section with one observation per trial. Enrollment represents the cumulative number of participants recorded for each completed trial, rather than an annual recruitment flow.

Table 1: Documented sample construction

Stage	Units	Observations	Reason or Rule
Verified accessible records	2 trials	2	Identifiable registrations with complete focal variables
Documentary exclusions	2 medicine candidates	0	DSP1181 and DSP0038 lacked identifiable NCT records in the screening documentation
Integrated and checked sample	2 trials	2	Unique trial identifiers and complete design and enrollment fields
Final descriptive sample	2 trials	2	Both verified records retained for comparison

The documentary exclusions identify unavailable candidate records rather than losses from the two observed trial rows. The accessible records constitute selected cases, not an enumerated global population. Consequently, geographical coverage describes the retained trials rather than the international distribution of AI designed medicines.

3.2 Data Integration, Cleaning, and Quality Assurance:

The NCT identifier served as the linkage key between each medicine, its registration record, and its supporting source information. Integration retained one row per identifier. Medicine names remained descriptive labels, preventing spelling differences from creating additional observations. This separation between identifiers and descriptive fields follows the registry data organization illustrated by Tasneem et al., 2012. The present dataset was assembled directly from registry records.

Checks confirmed two unique identifiers and no duplicate trial rows. All four focal variables were populated in both observations. Enrollment values were positive integers and explicitly classified as actual. Both records indicated completed status, and recorded start dates preceded completion dates. Allocation, masking, arm counts, and enrollment were reconciled with the downloaded registry fields. No observations were removed during these checks.

Source categories were preserved without recoding masking into a numerical quality score. Dates remained separate fields, and enrollment remained a participant count. No imputation, interpolation, zero substitution, trimming, or winsorization was applied. The recorded values required no frequency conversion or aggregation across calendar periods.

The retained records are updated registry descriptions of completed trials. Their design fields therefore represent the retrieved record versions rather than archived versions fixed at trial initiation. The comparison uses these fields to describe the completed records. Selection on completion also defines the scope of interpretation: the sample describes completed cases rather than the full development pipeline.

3.3 Variable Measurement, Construction, and Validation:

Clinical trial design is operationalized through allocation, masking, and registered arm count. These indicators remain separate observed characteristics. Actual enrollment is the recorded number of participants enrolled in each trial. The distinction between trial organization and participant accounting is consistent with Schulz et al., 2010, who identify allocation procedures, intervention groups, and participant flow as separate reporting elements.

Table 2: Variable dictionary

Variable or Indicator	Analytical Role	Definition and Construction	Source and Identifier	Unit and Frequency	Transformation and Direction	Missing Value Rule	Coverage and Limitation
Allocation	Design characteristic	Registry designation of treatment assignment	ClinicalTrials.gov, both NCT records; design Info. allocation	Category, once per trial	Original category retained; no numerical direction	None missing; no imputation	Randomized in both observations
Masking	Design characteristic	Overall registry designation of concealed treatment assignment	ClinicalTrials.gov, both NCT records; design Info. Masking Info. masking	Category, once per trial	Original category retained; categories are not quality scores	None missing; no imputation	One quadruple designation and one double designation
Registered arms	Design characteristic	Count of entries in arms Interventions Module. Arm Groups	ClinicalTrials.gov, both NCT records	Number of arms, once per trial	Untransformed count; larger values indicate more registered arm entries	None missing; no imputation	Registered arms do not enumerate every dose cohort
Actual enrollment	Enrollment measure	Enrollment Info. count where enrollment Info. type equals ACTUAL	ClinicalTrials.gov, both NCT records	Participants, once per completed trial	Untransformed count; larger values indicate greater recorded enrollment	None missing; no imputation	Aggregate enrollment without participant level characteristics

Masking requires interpretation at the level recorded. EXS21546 carries an overall quadruple designation, although its protocol description identifies double blind procedures in two parts and open procedures in another. The dataset retains both the overall designation and this qualification. Similarly, registered arm count describes the listed intervention structure rather than every procedural subdivision. Chan et al., 2013, distinguish intervention procedures, trial structure, and sample size justification within protocol documentation, supporting these measurement distinctions.

Table 3: Descriptive statistics for numerical variables

Variable	Valid Observations	Mean Sample	Standard Deviation	Median	Minimum	Maximum
Registered arms	2	2.50	0.71	2.50	2	3
Actual enrollment	2	71.00	9.90	71.00	64	78

Both trials report randomized allocation. Each masking category occurs once. Total reported enrollment is 142 participants across the two records. Standard deviations describe dispersion between the retained observations.

3.4 Analytical Framework, Identification, and Reproducibility:

The analytical framework is descriptive. We first summarize the recorded design characteristics and then compare actual enrollment across the two trial configurations. Categorical variables are reported through counts and proportions. Numerical variables are summarized through valid counts, means, sample standard deviations, medians, and observed ranges. The direct comparison preserves the trial as the unit of analysis. EXS21546 reports three registered arms and 64 participants, while INS018_055 reports two registered arms and 78 participants. The latter therefore records 14 more participants. This difference describes the observed configurations without attributing the enrollment difference to allocation, masking, or arm count.

Reproducibility rests on the two stable NCT identifiers, preserved registry categories, documented field mappings, and retained source links. Summary calculations were independently recomputed from the two observation rows and reconciled with the workbook totals. Goodman et al., 2016, distinguish transparent computational procedures from independent replication; the checks implemented here establish the reproducibility of the reported arithmetic. The workbook retains the observation table and accompanying measurement notes. Consistent trial identifiers link each measure to its source, while separate date fields distinguish trial conduct from record maintenance and retrieval. This structure keeps the descriptive comparison aligned with the recorded definitions and available observations.

4. Methods:

4.1 Research Design and Comparative Logic:

This analysis adopted a descriptive comparison of two completed phase 1 trials involving AI designed small molecule medicines. The unit of analysis was the registered trial. EXS21546 and INS018_055 constituted

the two cases, identified by NCT04727138 and NCT05154240, respectively. The comparison examined their recorded design configurations and actual enrollment within the eligibility window from 2010 to 2022.

The analytical purpose was to characterize allocation, masking, and registered arm count, then quantify the enrollment difference between the cases. Both trials reported randomized allocation, while their masking designations, arm counts, and enrollment totals differed. These characteristics supplied the observed contrasts. Comparisons retained the trial as the analytical unit and described differences between complete configurations. ClinicalTrials.gov records provided structured information linked through stable identifiers. Zarin et al., 2011, describe the registry infrastructure supporting the examination of clinical research information. Here, the records supported a retrospective description of completed trials. The analysis interpreted differences at the case level without assigning an independent causal contribution to any design characteristic.

4.2 Sample and Measurement Alignment:

The sample construction documented in Table 1 yielded two trial observations, both retained throughout the analysis. The variable dictionary in Table 2 governed measurement. Each focal field was populated in both records, so all descriptive calculations used the same sample.

Allocation and masking remained categorical registry designations. Frequencies summarized their occurrence without imposing a numerical ranking. Registered arm count was obtained by counting entries in the armGroups field. Actual enrollment was taken from enrollmentInfo.count, conditional on enrollmentInfo.type being ACTUAL. This restriction aligned the comparison with recorded participation rather than planned recruitment.

Interpretation preserved distinctions between registered arms, dose cohorts, and trial parts. The overall masking designation was read alongside its procedural description. For EXS21546, this included the distinction between masked procedures in some parts and open procedures in another. Chan et al., 2013, distinguish trial structure, intervention procedures, and sample size justification within protocol documentation. These distinctions supported interpreting each recorded measure according to its specific meaning.

4.3 Descriptive Calculations and Comparison Procedures:

Analysis proceeded from categorical summaries to numerical summaries and then direct comparison. Allocation and masking were reported as counts and proportions using two trials as the denominator. Registered arms and actual enrollment were summarized through valid observation counts, arithmetic means, medians, sample standard deviations, minima, and maxima. Sample standard deviations used the number of observations less one as the variance denominator. The absolute enrollment contrast was calculated as:

$$\Delta_N = N_B - N_A$$

Here, Δ_N denotes the difference in recorded participants, N_A denotes actual enrollment in EXS21546, and N_B denotes actual enrollment in INS018_055. Equation 1 fixes the comparison order and expresses the contrast in participants. The relative enrollment contrast was calculated as:

$$R_N = 100\frac{\Delta_N}{N_A}$$

Here, R_N denotes the percentage difference relative to EXS21546. Equation 2 retains the same comparison direction and uses EXS21546 enrollment as the explicit denominator. Each trial's share of combined reported enrollment was calculated by dividing its enrollment by the sum across both records and multiplying by 100.

All trial observations contributed equally to summaries of trial characteristics. Enrollment shares represented the distribution of reported participants across records rather than analytical weights. Calculations retained their numerical precision until presentation, with percentages and standard deviations rounded to two decimal places. Python version 3.12.14 and its standard statistics library were used to recompute the numerical summaries.

4.4 Verification, Reproducibility, and Interpretation:

Verification examined identifier uniqueness, focal field completeness, numerical consistency, and agreement with the downloaded registry fields. Checks confirmed distinct trial identifiers, positive integer enrollment values, actual enrollment classifications, completed status, and start dates preceding completion dates. Registered arm counts were reconciled with the corresponding arm entries. No observations were removed during these checks, and no imputation, interpolation, zero substitution, trimming, or winsorization was applied.

Numerical summaries were independently recomputed from the two observation rows and reconciled with the workbook totals. The absolute and relative contrasts were checked using the stated comparison order and denominator. Source categories were preserved throughout processing, while procedural qualifications remained available in the accompanying notes.

The workbook documents identifiers, source links, field mappings, measurement definitions, and summary calculations. These materials support tracing each reported comparison to its constituent records. Goodman et al., 2016, distinguish transparent computational procedures from independent replication; the verification undertaken here concerns the reproducibility of the recorded comparisons and their arithmetic.

Interpretation remained specific to the two selected completed trials. Observed ranges described differences between these records. The resulting evidence answered the research questions through documented configurations and enrollment contrasts, with conclusions bounded by the case selection and recorded measurement definitions.

5. Findings:

This analysis compares allocation, masking, registered arm count, and actual enrollment across two completed phase 1 trials. The findings establish the recorded design configurations before examining the magnitude of enrollment differences. The research questions are resolved through a direct comparison of the two verified trial records.

5.1 Sample Composition and Recorded Design Characteristics:

The retained sample comprises EXS21546 in the United Kingdom and INS018_055 in New Zealand. Each trial contributes one observation, and both records contain complete values for the four focal measures. Enrollment is explicitly classified as actual in both records. This classification matters because the comparison concerns recorded participation rather than recruitment targets. Zarin et al., 2011, describe the distinction between registration information and reported trial results within ClinicalTrials.gov, supporting careful interpretation of the fields used in registry analysis.

Table 4: Trial configurations and actual enrollment

Indicator	EXS21546	INS018_055
Registry identifier	NCT04727138	NCT05154240
Country	United Kingdom	New Zealand
Phase	Phase 1	Phase 1
Allocation	Randomized	Randomized
Overall registered masking	Quadruple	Double
Registered arms	3	2
Actual enrollment, participants	64	78
Share of combined reported enrollment	45.07%	54.93%

Both trials report randomized allocation. Allocation therefore represents a shared feature of the observed configurations. The design contrast lies in masking and registered arm count: EXS21546 records three arms and an overall quadruple masking designation, while INS018_055 records two arms and a double masking designation. This separation preserves the distinction between treatment assignment, concealment of assignment, and intervention structure. Schulz et al., 2010, treat these as separate elements of trial reporting rather than interchangeable indicators of design quality.

The masking designation for EXS21546 requires a precise reading. Its registry description identifies double blind procedures in two trial parts and open procedures in another. The overall quadruple designation consequently describes the registered masking roles without establishing that every part follows an identical procedure. This distinction is analytically relevant because masking concerns who knows the treatment assignment and when that information becomes available. Hróbjartsson et al., 2012, demonstrate the relevance of assessor masking to estimated intervention effects, reinforcing the need to preserve the procedural meaning behind a registry label.

The first research question is resolved by these observed configurations. The two selected trials share randomized allocation but differ in their overall masking designations and numbers of registered arms.

5.2 Enrollment Magnitude and the Design Contrast:

Combined reported enrollment equals 142 participants. Mean and median enrollment both equal 71 participants, with an observed range of 64 to 78 and a sample standard deviation of 9.90. These statistics summarize variation between the two trial totals.

INS018_055 enrolled 14 more participants than EXS21546. Using EXS21546 as the comparison base, this difference represents 21.88% greater enrollment. INS018_055 accounts for 54.93% of combined reported enrollment, compared with 45.07% for EXS21546. The absolute difference and relative comparison describe the same contrast on complementary scales.

The enrollment ordering differs from the arm count ordering. EXS21546 contains one additional registered arm, yet records fewer participants. Conversely, INS018_055 has fewer registered arms and greater actual enrollment. The observed configuration therefore shows that a larger registered intervention structure can coexist with a smaller participant total.

The distinction rests on what each measure captures. Registered arm count describes the listed intervention conditions, while enrollment describes participant volume across the trial. Arm entries do not enumerate every dose cohort or establish an equal distribution of participants across conditions. Chan et al., 2013, distinguish intervention procedures, trial structure, and sample size justification within protocol documentation. The present comparison retains those distinctions when interpreting the numerical pattern.

The second research question is resolved through the observed difference of 14 participants. Actual enrollment varies across the two recorded design configurations, with greater enrollment in the trial containing fewer registered arms.

5.3 Integrated Empirical Interpretation:

The principal finding is a divergence between registered arm count and actual enrollment within two trials sharing randomized allocation. The configuration with three arms records 64 participants, while the configuration with two arms records 78. Masking also differs, although the mixed procedures within EXS21546 qualify any simple comparison based on its overall designation.

These findings support an empirical distinction between design configuration and participant volume. The recorded design categories describe how a trial is organized; actual enrollment describes the number of participants recorded within that organization. Reading both together produces a more precise comparison than interpreting either in isolation.

The evidence answers the research questions at the level of the selected trial records. It establishes shared allocation, differentiated masking and arm structures, and a quantified enrollment contrast. The direction and magnitude of that contrast describe the two observed configurations without identifying an independent effect of any design characteristic.

6. Discussion:

More registered arms did not correspond to greater enrollment in the two observed trials. Table 4 identifies a design contrast in which the trial with fewer arms enrolled 21.88% more participants. The contribution of this analysis is the documented separation between intervention structure and participant volume within two AI designed medicine trials. This distinction matters because clinical development is often discussed through indicators that summarize different activities. Bender and Cortés Ciriano, 2021, distinguish computational achievements from their relevance to drug development. The present comparison adds a clinical reporting perspective: AI involvement identifies the discovery context, while trial design and enrollment require separate empirical description. The evidence provides a comparison of these cases rather than a general relationship across AI designed medicines.

The shared use of randomized allocation establishes a common design feature without making the trials organizationally equivalent. Table 4 shows that different masking designations, arm structures, and enrollment totals coexist under that shared allocation category. Experimental design theory assigns randomization a specific function in treatment assignment; it does not imply uniformity across other protocol dimensions. Bothwell et al., 2016, explain how randomized trials have developed within scientific and institutional arrangements that shape evidence production. Here, the implication is that a common methodological label provides only part of the information needed for comparison. Assessments of clinical development should therefore preserve the distinctions between assignment procedures, intervention conditions, and participant counts.

The divergence between arm count and enrollment also clarifies the conceptual limits of structural indicators. Registered arms describe listed intervention conditions, whereas enrollment measures participant volume. Table 4 demonstrates that these dimensions have different orderings across the selected cases. Getz and Campo, 2018, characterize protocol complexity through multiple operational dimensions, including procedures, visits, and investigative workload. Their findings establish a broader conception of complexity than arm count alone. The present evidence contributes a narrower but concrete observation: the number of registered arms does not reproduce the enrollment ordering of these two trials. This distinction supports retaining design indicators separately rather than combining them into an undifferentiated measure of clinical development scale.

The masking information reveals a further distinction between an overall registry category and the procedures operating within individual trial parts. Although Table 4 records a quadruple designation for EXS21546, its accompanying description specifies different masking arrangements across parts. The analytical insight concerns the level of aggregation: a single category can coexist with procedural variation within the same trial. Viergever et al., 2014, show that the usefulness of registry information depends on the specificity of recorded details. The present comparison illustrates why categorical extraction should remain linked to explanatory text. For registry analysts and reviewers, inspecting both fields preserves the meaning of the recorded design and avoids treating an overall designation as a uniform protocol characteristic.

The international relevance lies in the comparability of evidence across research settings. The United Kingdom and New Zealand records share a registry structure, allowing consistent comparison of allocation, masking, arms, and enrollment. Their inclusion does not establish differences between national clinical research systems. Viergever and Li, 2015, examine international registration patterns at a broader scale; this analysis instead examines how individual registered configurations differ within a shared reporting system. Together, these perspectives identify distinct requirements for international evidence assessment: geographical coverage establishes where research is represented, while field definitions establish what can be compared. The practical implication is to report participant volume alongside clearly defined design characteristics and retain procedural qualifications when interpreting registry categories.

7. Conclusion and Implications:

International assessments of AI designed medicines depend on interpreting clinical evidence at the level it represents. This analysis shows that shared experimental features can coexist with different intervention structures and participant volumes. Its contribution is a documented distinction between the organization of human evaluation and the scale of participation within two completed trials. The comparison also reveals that an overall registry designation can encompass different procedures within a single protocol. These observations sharpen the application of experimental design principles by preserving distinctions between recorded categories and their procedural meaning. For sponsors and research managers, the implication is to examine complete trial configurations before comparing development activity or informing resource decisions. For registry administrators, the evidence supports presenting summary classifications alongside explanations of procedural variation. For reviewers and evidence analysts, it supports checking categorical fields against accompanying descriptions before drawing comparisons across candidates or settings. Operationally, retaining stable identifiers, explicit definitions, and linked procedural notes makes these comparisons traceable. The broader social relevance lies in more accountable communication about emerging medicines. Clear separation of what records describe can help research institutions, clinicians, and public audiences interpret development claims with greater precision. These implications concern evidence interpretation across settings rather than demonstrated improvements in clinical performance.

The two-case cross section provides a basis for expanding the comparison across a larger, systematically assembled cohort. Longitudinal registry versions would distinguish initial plans from subsequent amendments and completed participation. Protocol level extraction could identify procedural differences concealed by overall classifications. Broader geographical coverage would permit assessment of institutional variation without treating individual trials as national representatives. Future analyses could examine recruitment duration, eligibility requirements, dose cohorts, and planned participation where these measures are consistently available. Such extensions would enable assessment of whether the observed contrasts recur and whether specific organizational features explain differences across clinical development settings.

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