Clinical Trial Compliance Analysis Report

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Document Information

- **Protocol:** a0dc5d84-0c24-49fa-9265-87fbedd86b0d.txt
- **Requirements:** requirements_diabetes_study.txt

Executive Summary

Overall Compliance: 58.3% (LOW)

Metric	Count
Total KPIs	6
Followed	2
Partial	3
Not Followed	1

1 KPI(s) need immediate attention.

Detailed Analysis

STRATIFICATION FACTORS

Status: PARTIAL | **Confidence:** 60%

Analysis: The requirements partially meet the protocol conditions for stratification factors. The evidence indicates that stratified randomization based on baseline HbA1c levels is mentioned, but it lacks the specific thresholds (<8.5% vs ≥8.5%) required by the protocol. Additionally, there is no mention of stratification by background diabetes medication (metformin monotherapy vs combination therapy), which is a critical component of the protocol conditions.

Gaps: 1. Lack of specific stratification thresholds for baseline HbA1c (<8.5% vs ≥8.5%). 2. Absence of stratification by background diabetes medication (metformin monotherapy vs combination therapy).

RANDOMIZATION VISIT

Status: NOT_FOLLOWED | **Confidence:** 60%

Analysis: The requirements document does not fully meet the conditions set in the protocol for randomization. The first condition regarding the use of an interactive web response system (IWRS) and a 1:1:1 randomization ratio is not mentioned at all in the requirements, resulting in no coverage. The second condition about stratification is partially met as the requirements document only addresses stratification by baseline HbA1c levels but omits stratification by background diabetes medication.

Gaps: 1. No mention of IWRS or 1:1:1 randomization ratio in the requirements document. 2. Lack of stratification by background diabetes medication (metformin monotherapy vs combination therapy) in the requirements document.

INCLUSION CRITERIA

Status: PARTIAL | **Confidence:** 80%

Analysis: The compliance assessment reveals that 5 out of 6 conditions are fully met according to the evidence provided. The condition regarding age and gender criteria is not addressed in the requirements document, which constitutes a significant gap. Therefore, the overall compliance is partial as the coverage is approximately 83%.

Gaps: The requirements document does not specify any age range or gender criteria for the patient population, which is a gap in meeting the inclusion criteria.

EXCLUSION CRITERIA

Status: FOLLOWED | **Confidence:** 95%

Analysis: All exclusion criteria conditions from the protocol have been fully met according to the evidence provided. Each condition has corresponding evidence with

full coverage, indicating that the requirements align with the protocol's exclusion criteria.

Gaps: No gaps identified; all conditions are fully covered.

DOSING SCHEDULE

Status: FOLLOWED | **Confidence:** 100%

Analysis: All conditions from the protocol regarding the dosing schedule have been fully met according to the evidence provided. Each condition is supported by clear and complete evidence with appropriate citations from the protocol sections. There are no gaps identified in the requirements, indicating full compliance with the protocol's dosing schedule.

Gaps: None

VISIT SCHEDULE

Status: PARTIAL | **Confidence:** 80%

Analysis: The compliance assessment shows that the requirements document fully covers the conditions for measuring blood pressure, heart rate, and weight at each visit, as well as the 12-lead ECG schedule. However, it does not specify the duration of the screening period or the follow-up period, which are critical components of the protocol. Therefore, the overall compliance is partial, as only 60% of the conditions are fully met.

Gaps: 1. The requirements document does not specify a screening period of 2 weeks. 2. The requirements document does not specify a follow-up period of 4 weeks.

Metadata

- **Analysis Method:** 3-Step KPI Compliance Analysis
- **KPIs Analyzed:** 6

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