

Nipocalimab in Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Updated Diagnostic Adjudication Findings From the Phase 2/3 ARISE Study

Kenneth Gorson, MD,¹ Thomas Harbo, MD, PhD,² Jonathan Katz, MD,^{3*} Richard A. Lewis, MD,⁴ Bob Murray, MSc,⁵ Phillippe Linscheid, PhD,⁶ Mojgansadat Borghei,⁷ Lisa Ford, MD⁸

¹Department of Neurology, Tufts University School of Medicine, St. Elizabeth's Medical Center, Boston, MA, USA; ²The Department of Neurology, Aarhus University, Aarhus, Denmark; ³Department of Neurology, California Pacific Medical Center, San Francisco, CA, USA; ⁴Department of Neurology, Cedars-Sinai Medical Center, Los Angeles, CA, USA; ⁵Johnson & Johnson, High Wycombe, United Kingdom; ⁶Actelion Pharmaceuticals Ltd, Part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Allschwil, Switzerland; ⁷Johnson & Johnson, Beerse, Belgium; ⁸Johnson & Johnson, Titusville, NJ, USA



<https://www.congresshub.com/Neuroscience/AANEM2026/Nipocalimab/Katz>

Scan the QR code
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

*Presenting author

Introduction

- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) is a rare, autoimmune disorder of the peripheral nervous system characterized by progressive muscle weakness and impaired sensory function^{1,2}
- CIDP has heterogeneous features, including a typical phenotype (typical-CIDP) and variants (variant-CIDP). Typical-CIDP accounts for approximately 50–60% of cases, while variant-CIDP accounts for about 40–50%.^{3,4} Diagnosis of CIDP is challenging owing to its wide spectrum of clinical presentations, often leading to misdiagnosis in nearly 50% cases^{5,6}
- The ongoing ARISE phase 2/3 multicenter, randomized, double-blind, placebo-controlled, withdrawal study (NCT05327114) evaluates the efficacy and safety of nipocalimab, a neonatal fragment crystallizable receptor blocker, in adults with CIDP
- An external independent 4-member CIDP Adjudication Committee (CAC) was established to strengthen diagnostic rigor and confirm CIDP diagnosis, per the 2021 European Academy of Neurology/Peripheral Nerve Society guidelines, before enrollment in the ARISE study⁶

Objective

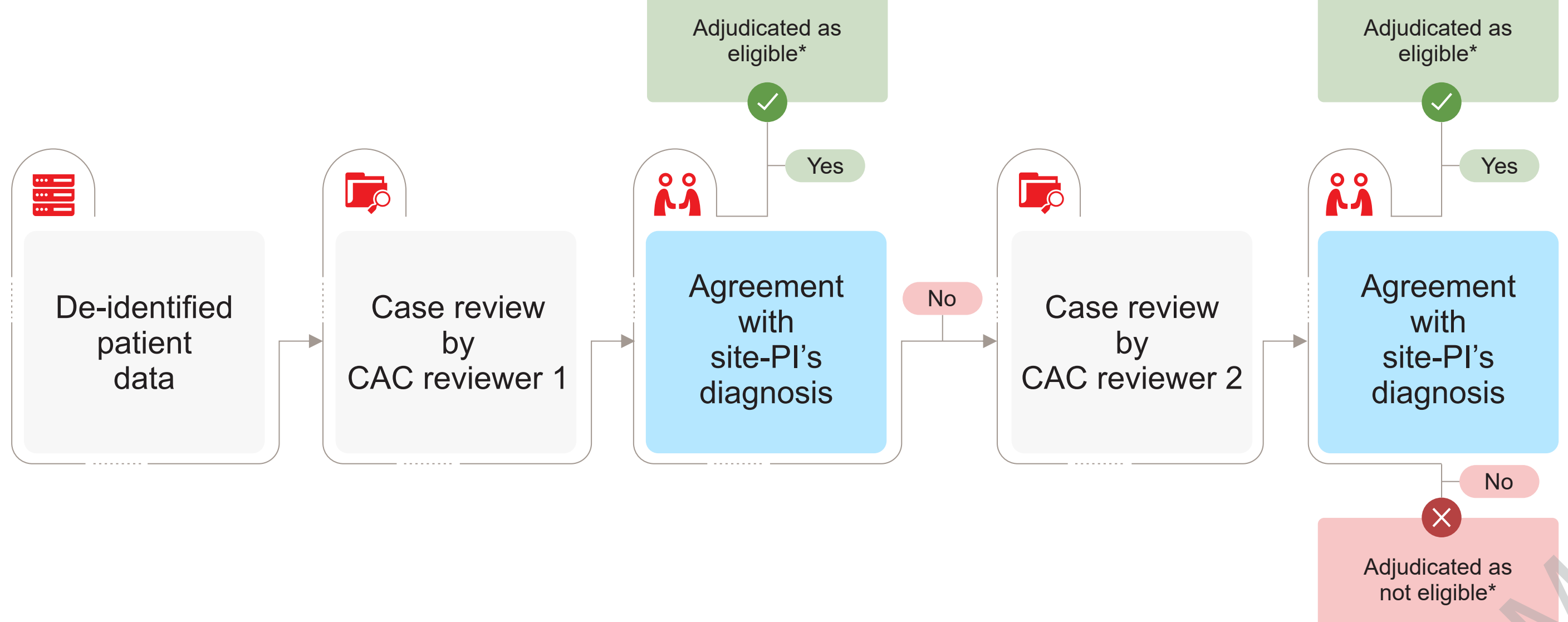
- To report updated demographics, CAC adjudication outcomes, and CIDP-type distribution of ARISE participants

Methods

CAC Adjudication Process

- De-identified participant data submitted by site principal investigators (site-PI) are reviewed by the CAC-reviewers (Figure 1).

Figure 1. CAC adjudication process



Results

Baseline Characteristics

- In 214 participants, the median age was 57 years and the majority were male (145 [67.8%]); Table 1
- The majority of participants were untreated (91 [42.5%]) or received prior IVIg (87 [40.7%])

Table 1. Baseline characteristics of all participants

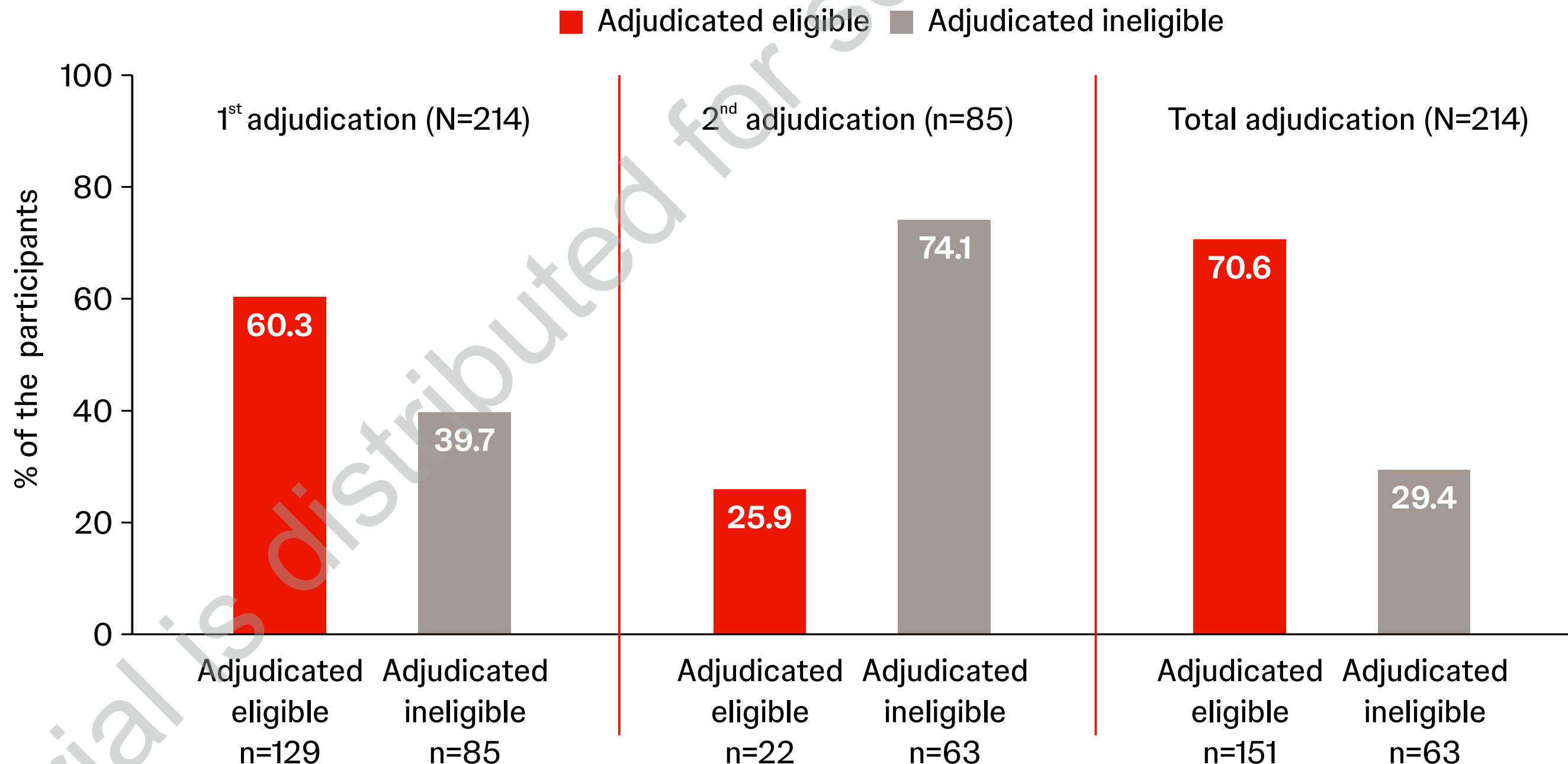
Characteristics (N=214)	All (N=214)	Eligible (n=151)
Age, year, median (range)	57 (20–90)	56 (20–90)
Sex, Male, n (%)	145 (67.8)	106 (70.2)
Region, n (%)		
APAC	101 (47.2)	75 (49.7)
EMEA	86 (40.2)	61 (40.4)
NA	24 (11.2)	12 (7.9)
LATAM	3 (1.4)	3 (2.0)
CIDP participants with diabetes mellitus, n (%)	37 (17.3)	29 (19.2)
Time since diagnosis, years, median (range)	1.5 (0.0–25.9)	1.2 (0.0–25.9)
Race, n (%)		
Asian	102 (47.7)	76 (50.3)
White	76 (35.5)	50 (33.1)
Not available	34 (15.9)	23 (15.2)
American Indian or Alaska Native	1 (0.5)	1 (0.7)
Black or African American	1 (0.5)	1 (0.7)
Prior medication, n (%)		
CS	36 (16.8)	23 (15.2)
IVIg	87 (40.7)	65 (43.0)
Untreated	91 (42.5)	63 (41.7)

APAC=Asia-Pacific, CIDP=Chronic inflammatory demyelinating polyradiculoneuropathy, CS=corticosteroids, EMEA=Europe, the Middle East and Africa, IVIg=intravenous immunoglobulin, LATAM=Latin America, NA=North America.

Diagnostic Adjudication

- Of first 214 participants, CAC adjudicated 151/214 (70.6%) participants as eligible (Figure 2)
 - Agreement of first CAC-reviewer with site-PI adjudicated 129/214 (60.3%) participants as eligible
 - For 85/214 (39.7%) disagreed cases, the agreement of second CAC-reviewer with site-PI adjudicated 22/85 (25.9%) participants as eligible and remaining 63/214 (29.4%) participants were adjudicated as ineligible

Figure 2. Diagnostic Adjudication (N=214)



- The majority participants were of typical-CIDP type (1st adjudication: 67.4% participants, 2nd adjudication: 72.7% participants), Table 2

Table 2. Participants with typical vs variant-CIDP

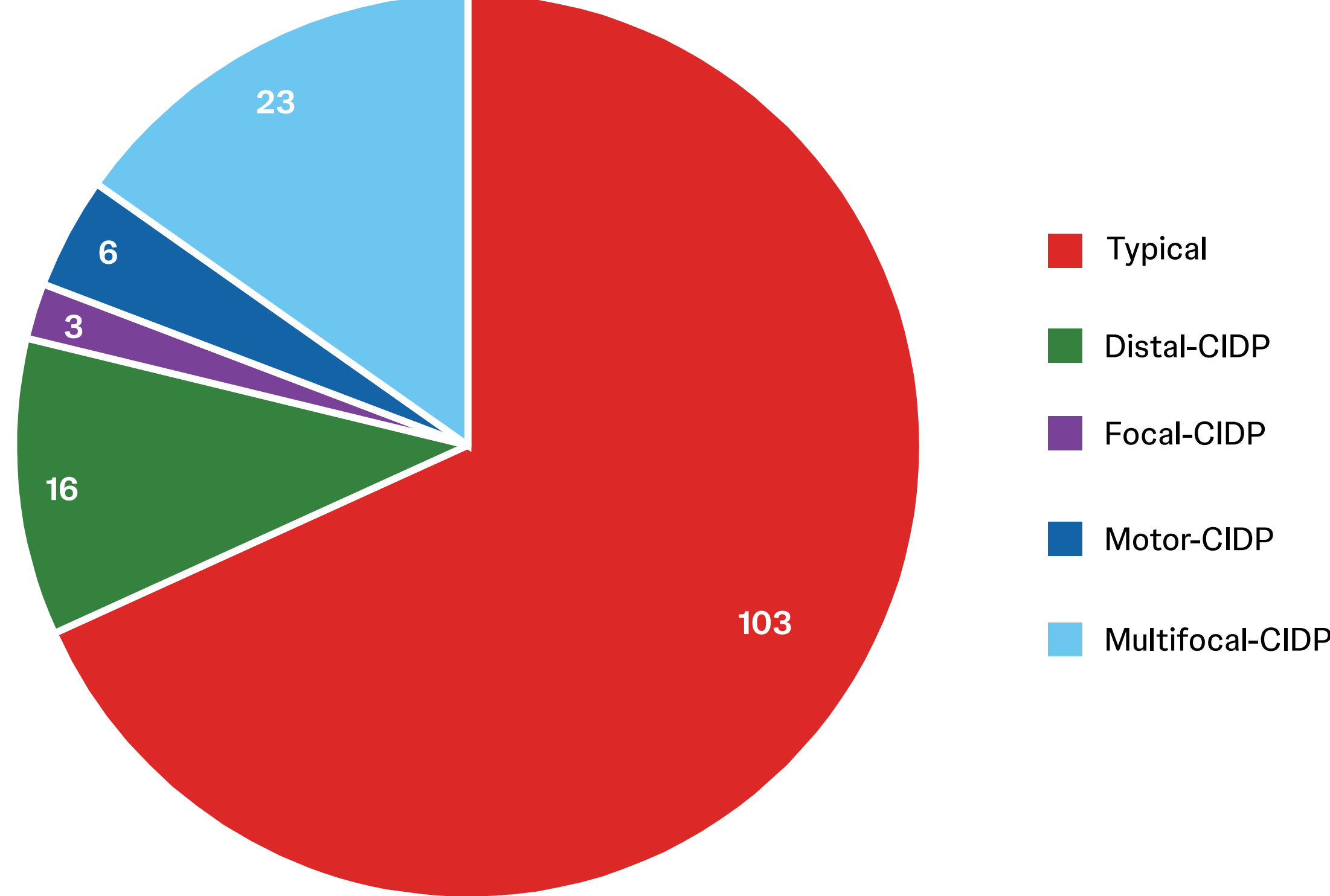
CIDP type	Adjudicated eligible		
	1 st Adjudication n=129	2 nd Adjudication n=22	Total Adjudication N=151
Typical-CIDP, n (%)	87 (67.4)	16 (72.7)	103 (68.2)
Variant-CIDP, n (%)	42 (32.6)	6 (27.3)	48 (31.8)

CIDP=Chronic inflammatory demyelinating polyradiculoneuropathy.

CIDP Subtypes in Eligible Participants

- Among the 151 eligible participants, 48 (31.8%) were classified as variant-CIDP based on adjudicator's diagnosis (Figure 3)
- Multifocal-CIDP was the most common subtype followed by distal-CIDP, motor-CIDP, and focal-CIDP, respectively

Figure 3. CIDP sub-types in eligible participants (N=151)

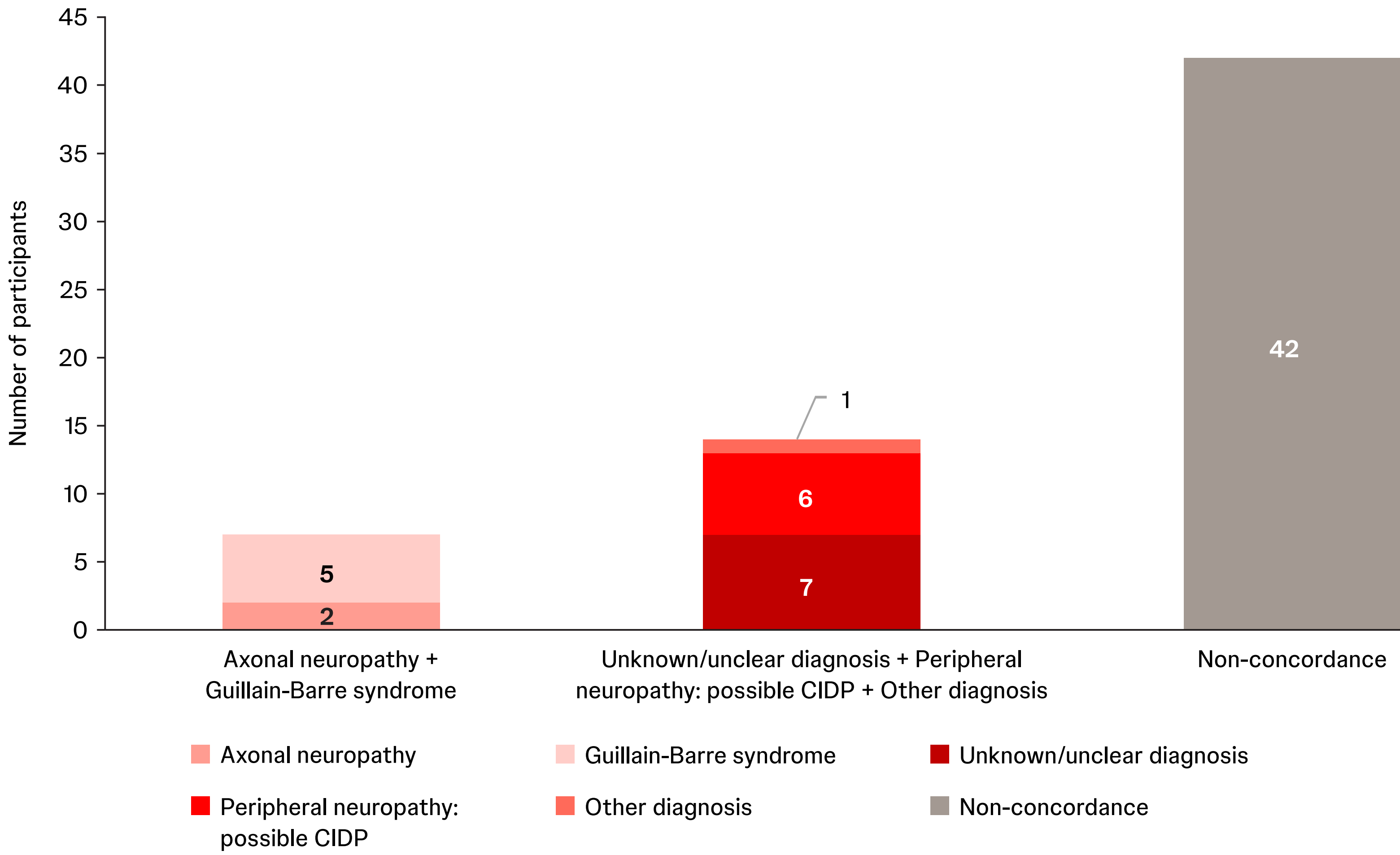


CIDP=Chronic inflammatory demyelinating polyradiculoneuropathy.

Reasons for Adjudicating Ineligible

- Amongst 63 ineligible participants, the most common reason was non-concordance between adjudicators (42 [66.7%]), followed by unknown/unclear diagnosis (7 [11.1%]) and peripheral neuropathy (possible CIDP/demyelination not meeting diagnostic criteria for CIDP) (6 [9.5%]) (Figure 4)

Figure 4. Reasons for adjudication as ineligible (N=63)



Note: "Unknown/unclear"=ineligible cases for which both adjudicators agreed the diagnosis is "unknown/unclear". "Peripheral neuropathy"=possible CIDP/demyelination not meeting diagnostic criteria for CIDP. "Non-concordance"=Non-concordance between adjudicators (i.e., different reasons between adjudicators). CIDP=Chronic inflammatory demyelinating polyradiculoneuropathy.