

# The Nuances of Patient Selection: Why Some Trials Need Eligibility Adjudication

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**Patient selection can be a nuanced process in clinical trials, particularly those involving therapeutic areas with more complex or subjective inclusion/exclusion criteria.**

Determining patient eligibility may often depend on factors that require clinical expertise in such areas as disease progression, comorbidities, genetic mutations, and disease severity.

An eligibility adjudication committee helps to ensure there is a standardized approach to assessing patient eligibility across different sites and geographic locations. As clinical experts serving on the adjudication committee, they hold the expertise to help determine whether a patient is appropriate and meets criteria for the study, per predefined criteria. By meticulously and expeditiously analyzing specific clinically relevant data during the screening process, including medical history, lab results, and information from the investigator, the committee can decide whether a patient meets certain protocol-defined criteria.

The right eligibility adjudication committee plays a critical role in ensuring trial success by providing an independent and unbiased assessment of patient eligibility. The committee's expertise, combined with a robust adjudication process, helps ensure that the patient population meets the intended criteria, and that eligibility is not influenced by the interests of trial sites. This, in turn, helps researchers accomplish the intended purpose of the clinical trial.

Although there are many trials that benefit from the use of an eligibility adjudication committee, it may be of particular use for trials that are subject to regulatory scrutiny or rare disease trials, given there is limited data from which standardized decision can be made.

## What the experts are saying

"In trials with eligibility complexities, often syndromic inclusion or exclusion criteria, adjudication of trial eligibility may be helpful in certain situations", according to **Jonathan Seltzer, MD, FACC**, Founder, WCG ACI and Executive Director, Cardiac Research Consortium. "Variability in interpretation of specific inclusion or exclusion criteria, as seen in diseases that lack standardized global diagnostic definitions, may lead to a more heterogeneous study population than desired. This could possibly necessitate an increase in study population or potentially obscure the study results."



## Why It's Important



### **Patient safety:**

Eligibility decisions have a profound impact on a participant's safety and well-being.



### **Patient ethics:**

By providing expedited eligibility criteria decisions, the principal investigator can alert the subject in a timelier manner.



### **Precision:**

Eligibility adjudication committees consist of specialized and experienced experts with knowledge of the disease, patient population and specific criteria for eligibility. Leveraging their expertise ensures the integrity and precision of the critical screening process.



### **Reduced site burden:**

The adjudication process adds an additional layer of expertise, oversight and quality control, ensuring the investigator sites have access to experts to ensure that trial participants meet the required criteria and minimizing the potential for protocol deviations or enrollment delays.



### **The right patients, on time:**

With the right partner, the sponsor can be assured they will have the right mix of eligible patients enrolled within an appropriate timeframe.



### **Independent adjudication:**

These committees ensure unbiased, evidence-based eligibility decisions.



## The Process

WCG works backwards from critical study timelines to define the workflow to achieve decision results on time.

Once screening begins and the eligibility adjudication process is underway, WCG tracks decision result turnaround time, ensuring that study sites have real-time access to eligibility decision results.



## Timing Matters

Eligibility adjudication requires prompt turnaround time and access to decision data. The results have a direct impact on patients who want to participate in a potentially lifesaving or life-altering clinical trial.

The case study below illustrates how WCG deployed an eligibility adjudication committee to enroll patients in a multiple sclerosis trial.

### Eligibility Adjudication in Action: A Case Study



WCG was chosen to provide eligibility for a multiple sclerosis trial aimed at determining the efficacy of a gene therapy compared to a placebo in delaying disability progression in patients with non-relapsing secondary progressive multiple sclerosis (nrSPMS).

The adjudication committee was charged with confirming that potential subjects had a previous diagnosis of nrSPMS, and a documented progression of disability within the 12 months prior to screening.



## The Challenges

The sponsor and CRO, seeking an independent provider, turned to WCG based on its expertise in eligibility and other types of adjudication across an array of therapeutic areas, including MS, and across various interventions, including gene therapy.

- **Expedited startup:** The sponsor and CRO needed the eligibility adjudication committee set-up and ready for first patient within eight weeks of the contract being awarded. Given that first-patient-in is typically a moving target, the sponsor needed someone who could change course quickly.
- **Tight voting schedule:** Committee members were directed to vote within two days to achieve turnaround targets.
- **Multiple inclusion criteria:** The committee had to assess two eligibility criteria utilizing available data and completing their voting assessment within tight turnaround times.
- **Global patients:** The sponsor and CRO needed to be sure that the assessments were conducted consistently across sites and regions, taking into consideration geographic differences in standard of care and available records.



## The Solutions

WCG put in place people, processes, and technology to meet these challenges. WCG:

- **Established turnaround metrics** for each stage of the adjudication process to ensure critical deadlines were achieved leading up to first-patient-in.
- **Designed a data collection process** that minimized the burden on each site while obtaining clinically relevant information for the committee.
- **Contracted five expert members** to serve on the committee to ensure adequate member coverage.
- **Managed the committee process**, including executing the charter, scheduling and facilitating the kickoff meeting, and providing ongoing management of the adjudication data.
- **Supported sites** by developing site materials and putting in place a process to ensure the site knows when they can expect to receive the decision results for each patient.
- **Built the adjudication database** using WCG's AIMS [Adjudication Information Management System] platform to support the entire adjudication workflow while ensuring compliance with CFR PART 11 regulations.



## The Outcome

WCG's adjudication committee successfully reviewed 1,417 patients, of whom 1,361 qualified for the study. WCG completed this within the eight-week startup window, and the study began with no adjudication-related delays. This efficient process led to the client requesting WCG's management for eligibility adjudication in subsequent studies.

*Choosing the right study participants can make the difference between a successful trial and an unsuccessful one. To learn how WCG can ensure your complex trial has the right mix of participants, contact us using the link below.*

<https://www.wcgclinical.com/solutions/endpoint-adjudication-committee/#form>