



OVERCOMING THE BARRIERS TO CLINICAL TRIALS ACCESS

COURSE NOTES

INTRODUCTION

One in three persons may experience the onset of a neurological condition at some point in their lives.¹ The burden of neurological diseases is expected to expand as the world's population continues to age and grow, surpassing the toll of all other diseases, such as cardiovascular conditions. If current trends persist, the World Health Organization predicts that by 2030, illnesses primarily related to the brain would account for 50% of the global economic cost of disability.² Furthermore, neurological diseases have been the most difficult to comprehend and treat, and their effects are posing new difficulties for global health systems, economies, patients, caregivers, and their families.

Clinical research is making findings that allow neurologists to better diagnose and treat their patients. But the success of these studies is dependent on patient participation. And too often trials don't succeed, or are substantially delayed, due to low levels of patient participation.

While neurological conditions are prevalent, disabling and costly, for far too long they did not benefit from the investment in research necessary to discover new treatments and cures. But in recent years, investment in research has yielded new treatments for migraine headache, multiple sclerosis, Alzheimer's and rare neurological conditions. New therapies offer new promise for Europeans living with neurological conditions. Yet for every research success story there are dozens of failures. And one of the impediments to advancing the research is low levels of clinical trials participation.

CLINICAL TRIALS IN NEUROLOGY – AN OVERVIEW

In this section, Dr. Charles presented an overview of clinical trials, how they succeed and how barriers to access impact medical research.

Patient access starts with medical research. Clinical trials are an essential part of developing the new medicines, devices and diagnostics that improve health and quality of life worldwide. Clinical trials determine whether new treatments are safe and effective.

Robust enrolment is necessary for that research to succeed, but several challenges stand in the way, including:

- The public's lack of clinical trials awareness
- Costs incurred by participating patients
- Lack of engagement by health care providers

¹ World Health Organisation (WHO), Optimizing brain health across the life course: WHO position paper. Available here: <https://apps.who.int/iris/rest/bitstreams/1457108/retrieve>

² Mathers C. D., Loncar D. (2006). Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med. 3:e442. <https://doi.org/10.1371/journal.pmed.0030442>

- Persistent health disparities

These impediments are the first and most fundamental barrier to patients accessing the next generation of innovative treatments and cures.

POLICIES THAT SUPPORT PATIENT AND PROVIDER PARTICIPATION IN CLINICAL TRIALS

While the barriers are multifaceted, so too are the opportunities for policymakers, health care providers and patient advocates to improve access and advance medical innovation.

In this section, Professor Anthony Woolf reviewed policy solutions that permit patients greater access to clinical trials and make it easier for healthcare providers to participate in trials or support patients enrolling in trials. The presentation reviewed specific actions policymakers might make to address the access barriers detailed in the Section 1 presentation.

Earlier this year, GAfPA launched a White Paper on this topic entitled “Clinical Trials Access-Overcoming the Earliest Barrier to Treatment” which can be found [here](#), addressing what clinical trials access barriers exist and what actions can be taken to address them.

IMPROVING CLINICAL TRIALS ACCESS THROUGH GREATER AWARENESS

In this section, Anna Molinari shared a case study on how an awareness campaign can address a public health priority. Ms. Molinari reviewed how a government sponsored public awareness “Share Your Life, Share Your Decision” campaign dramatically raised the number of Americans who registered as organ donors. The presentation examined how a similar approach might raise public awareness about clinical trials and the opportunity to enrol in a study.

Public health awareness campaigns in the United States have been highly successful at educating, increasing awareness, and mobilizing the general public to act in ways that benefit their fellow citizens and society as a whole. In its [paper](#), the [Coalition for Clinical Trial Awareness](#) explores how the campaign to increase organ donations provides a model for public health awareness efforts.

ABOUT GAfPA

Established in 2014, the Global Alliance for Patient Access (GAfPA) is a non-profit organisation that provides a unique platform for health care stakeholders to convene, identify unmet needs, set advocacy priorities, and advance narratives about the value of patient-centred care to raise awareness and inform policy making. GAfPA has extensive experience

addressing unmet patient needs in policy conversations across various disease states and medical specialties including:

- Cardiology
- Rheumatology
- Oncology
- Neurology
- Immunology
- Rare Disease
- Infectious Disease

The policy issues impacting patient access which GAfPA prioritizes include health technology assessments, evidence-based practice, continuity of care, pharmacovigilance, health disparities and the value of innovation.

More information can be found in GAfPA's [annual report](#) and on GAfPA's [website](#).