

# The Emerging Role of Clinical Pharmacist in Clinical Trials

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**Abstract:** Over the last few years, the clinical pharmacy has significantly expanded its professional offerings. The clinical pharmacist has evolved into an important part of the healthcare team, promoting patient care via interactions with physicians and patients. The purpose of this study is to emphasize clinical pharmacists' significance in clinical research areas and to show the emerging role of pharmacists in trials. It is concluded that the characteristics of a pharmacist's interactions with other health care teams and Expertise in analytical, pharmacological, and pharmacologic terminology, pharmacovigilance, honesty in documentation, etc. will Impact physician-pharmacist collaboration and improve patient care and patient requirements in trials, and also enhance the clinical research study outcomes. The role of clinical pharmacists is diverse in the clinical research industry, they can work as clinical trial assistants, clinical research coordinators, or clinical research associates, and thus, can also streamline the activities of clinical trials ensuring that all the trials procedures are followed according to ICH-GCP guidelines, standard operating procedures, and regulatory requirements.

**Keywords:** CPs, EBM, DUEs, PMR, ADR, ASHP, WHO, INDs.

## 1. INTRODUCTION

Over the last several years, the clinical pharmacy has significantly expanded its professional offerings. We, as clinical pharmacists (CPs), can work in a multidisciplinary crew within a pharmaceutical practice. We collaborate with other healthcare experts, such as physicians and nurses, and are responsible for assessing a patient's health problems and suggesting answers and prescribing medicines to assist them. The function of a clinical pharmacist includes an excessive degree of choice-making because we are responsible for growing medication therapy, choosing medicine, and teaching patients on what they can do to improve

their health. Furthermore, clinical pharmacists also must make sure patients acquire the perfect dosage of medicine and examine all elements of treatment plans. We are able to participate in clinical studies as well as build a database for every medication.

CPs are on top of things at the latest developments in medicine and can make contributions correctly to clinical research tasks and different modern studies projects. <sup>(1)</sup>

In clinical trials, CPs may even function as lead investigators and patient instructors and can help patients take part more completely in clinical trial research.

Expertise in analytical, pharmacological, and pharmacologic terminology, pharmacovigilance, honesty in documentation, and the potential to tour widely are a few of the talents required to work in a clinical research organization. <sup>(2)</sup>

Historically, the role of the clinical pharmacist turned into commonly constrained to hospitals, clinics, and academic institutes, however, that is speedy developing and they're becoming greater without difficulty accessible to the public. This boom is coming approximately via the involvement of clinical pharmacists in reviewing medicine regimens and helping with recommendations on information hotlines to prevent medication errors in the future. Relying on the country or state of practice, a few clinical pharmacists also are capable of prescribing a few medications and the scope for these keeps to make bigger.

2. CLINICAL PHARMACISTS ARE THE PROFESSIONAL'S EXPERT IN THE THERAPEUTIC USE OF DRUGS WITHIN THE HEALTHCARE TEAM LIKE WITHIN THE FOLLOWING



Fig 1. showing the clinical pharmacist Expertise.

2.1) Evidence-Based Medicine(EBM): EBM is the multidisciplinary method to offer good care to the patient via the usage of the evidence of extensive published research. EBM allows selling the rational use of medicinal drugs ensuring that patients get hold of the right medicine in the proper dose for the right diagnosis at the right time at the bottom feasible value appropriate to their person necessities<sup>(3, 4)</sup>. The clinical pharmacist has a major role in this regard and has a deep knowledge of EBM and can make a big effect on the lives of the patients.

2.2) Medication Adherence: Medication adherence is an important factor to determine the efficacy of the prescribed medicines. One of the foremost roles of a clinical pharmacist is to review the medication and educate the patients so that you can reduce the medicine errors and provide knowledge to the patient this will improve medicinal drug adherence<sup>(7, 8)</sup>.

2.3) Drug Utilization Evaluations(DUEs): DUEs are research projects which are normally conducted by pharmacists. These projects' goal is to facilitate the rational use of medication within our patients. Basically, imparting insights on how medicines are used in patients and watch prescribing patterns by means of our physicians. DUEs are considered drug audits due to the fact pharmacists are ensuring the use of medication is suitable.<sup>(9)</sup>

2.4) Patient Counselling: From the clinical pharmacist's angle, patient counseling is the most essential work for patients. Patients have several queries concerning disease, medicines, lifestyle changes, nutrition, treatment, therapy period, and scientific gadgets like metered-dose inhalers for asthmatics or insulin pens for diabetics.

A clinical pharmacist may provide statistics on continuing treatment to the patient in an effort to guarantee drug supply, medication concordance aids, communication of unique troubles, proper dose monitoring, and minimal disturbance. And also can provide information on the patient's present clinical condition and educate him or on the safe and proper use of medications, Hence it will improve his /her treatment results.<sup>(2)</sup>

2.5) Documenting Pharmaceutical Care: Pharmaceutical care is the direct, responsible provision of medication-associated care for the motive of reaching exact effects that enhance a patient's quality of life.<sup>(14)</sup>

The expert movements of pharmacists which are supposed to ensure the secure and effective use of medication that may affect patient results ought to be documented in the Patient's Medical Record (PMR). ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records describe the kinds of information pharmacists should document in the PMR.<sup>(15)</sup>

2.6) ADR Monitoring and Reporting: Clinical pharmacists can play an essential position in the assessment of drug-drug interactions, drug-meals interactions, and ADR. Because they're drug professionals- having considerable expertise in pharmacological action, pharmaco-therapeutics, adverse reactions, and ailment pathophysiology could make drug therapy safer. They participated in ward rounds and collect all the information like patient medication records, suspected drugs, examples of ADR, and correspondent informer, which will assist in ADR monitoring and reporting.<sup>(16)</sup>

### 3. PHARMACIST IN CLINICAL TRIALS

According to the WHO, "clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes."

Over the last decade, there has been a giant boom in the number of clinical trials globally envisioned to be 440,759 studies researched in all 50 states and in 221 countries.

The latest seek on the scientific trial database showed that 7184 trials are registered for Covid-19 <sup>(13)</sup>. And this has unfolded a selection of the latest possibilities for the ones wishing to work in the research industry. The design, coordination, and analysis of a clinical trial require a multidisciplinary team which includes particularly the fundamental and sub-investigators, clinical research coordinators (CRC), studies pharmacists, and Clinical Research Associates (CRA), amongst others. <sup>(5)</sup> The person concerned in clinical research has to be accurately educated and trained according to worldwide ICH-GCP guidelines and regulatory requirements.

Within the clinical trials organization, CPs have suitable posts as clinical research coordinators, clinical

research Associates (CRA), studies statisticians, and higher positions (with optimal revel in).

Clinical pharmacists may even work as principal investigators and patient educators in clinical trials. pharmacists can play a position in improving patients' participation in clinical trial studies. The abilities needed to work clinical research corporation encompass knowledge of statistical, medical, and pharmacologic terms <sup>(10)</sup>, pharmacovigilance, sincerity in documentation, and capacity to journey considerably. <sup>(11)</sup>

Why Clinical pharmacist is needed in a clinical trial? Because we are using investigational new drugs INDs in trials. The correct control of INDs can also result in the fulfilment, or failure of a clinical study and the pharmacist is the most suitable team member for this undertaking. It's miles the pharmacists' function to make sure that the drug receipt is recorded inside the observation files or inside the interactive voice response tool. The pharmacist additionally has the primary duty of drug dispensing. <sup>(17)</sup> And it is legally, professionally, and ethically responsible to have a pharmacist in a clinical research crew.

The pharmacist can contribute to various types of clinical research like in the following beside with other healthcare professionals.

Pharmacokinetics	Drug used studies	Interaction
Adverse effects or safety	Efficacy	Health outcome
Pharmacoeconomics	Pharmacokinetics/ genomic	Quality-of-life
Pharmacodynamics	Pharmacoepidemiology	Stability or compatibility.

Table 1. Types of Clinical Pharmacy Research

Where does the pharmacist stand in clinical trials? For example a knowledge of the types of blinding in clinical trials, in double-blind absolutely everyone worried does not recognize which therapy the patients have been randomized to acquire. According to one research that's double-blinded study, crystalloids, or colloids for goal-directed fluid therapy in colorectal surgical treatment, published in the British journal of Anaesthesia in 2013, concluded that goal-directed fluid therapy is feasible with either crystalloid or hydroxyethyl starch (HES). Hence there may be no proof of a benefit in using HES over crystalloid. Here all studies crew is blinded besides the pharmacist who is Un-blind to the INDs. <sup>(12)</sup>

Evidence from several randomized trials indicates that pharmacist-pushed patient counseling, consultation,

disease instruction, and advice, as well as telephonic intervention, have progressed patients' self-care. As an example educating patients about managing rheumatoid arthritis empowers them in the knowledge of signs and symptoms of the disease and devising ways to reduce or limit aggravating factors. A randomized trial conducted by means of Petkova involved a community pharmacy-based totally, patient instruction program and proven progressed treatment outcomes in patients with Rheumatoid Arthritis <sup>(6)</sup>.

A randomized-controlled study is performed on patients with hemodialysis in which adherence to treatment recommendations is hard. This study concluded that providing clinical pharmacy education to hemodialysis patients improved adherence behavior and clinical consequences. This illustrates the

importance of clinical pharmacists as interdisciplinary crew members in dialysis care. <sup>(18)</sup>

Similarly, in a surgical orthopedic division, researchers concluded “a clinical pharmacist performed more comprehensive and more accurate drug histories than nurses. Based on the consequences of these, it has been proposed that pharmacy staffs may be exclusively positioned to improve both the quality of clinical research through involvement in medication reconciliation activities. <sup>(19)</sup>

However, a pharmacist in clinical trials is known as a clinical research pharmacist. A really perfect multidisciplinary approach in clinical research is that there are many contributors in trials but at least seven members should be there for a good clinical trial they are 1. Sponsor 2. Investigator, 3. Pharmacist, 4. Nurses, 5. CR Associate, 6. CR Coordinator, and 7. Bio-statistician; these seven members make a successful clinical trial research team.

#### 4. ROLES AND RESPONSIBILITIES OF CLINICAL RESEARCH PHARMACIST

As an integral member of the pharmacy crew, the Clinical Trials Pharmacist performs responsibilities which are following:

- Provision of expertise in drug composition and layout.
- Supervision of indications, dosage, administration, contraindications, destructive results, and interactions of investigational drugs (IDs).
- Protection of human subjects and their rights in compliance with IRBs.
- Recording of drug receipts and drug dispensing.
- Responsible to take unused medications from the patients and destruction of leftovers.
- Packaging, labeling, and substance analysis of IDs.
- Verification of lot range, expiry date, accurate use, posology, managing, garage, and ROA (in compliance with the sponsor).
- Provision of quality drugs that meet the sponsor's commands for trials.
- Pharmacist as CRC: helping the investigator to conform with the studies task necessities, aiming to acquire dependable trial effects.

- Pharmacist as CRA: ensuring the accuracy of clinical data and compliance with relevant laws.
- Performing move-purposeful obligations along with the ones of the oncology/iv admixture pharmacist, staff pharmacist, and patient care.
- Performing communication responsibilities.
- Performing education responsibilities.
- Performs other duties consistent with the job classification, as required. <sup>(20)</sup>

#### CONCLUSION

In clinical trials, the accurate control of INDs, ADR monitoring and reporting and patient counselling may lead to the success or failure of a clinical study and the clinical pharmacist is the most suitable team member for this task. We strongly believe that wherein there may be drugs there has to be a pharmacist.

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