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THE AWARE CONSUMER

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■ **IN FOCUS**
Clinical Research in India: Safety, Trust and the Growing Voice of Patients

PATIENT AS CONSUMER: Ethics, Rights and Participation in Clinical Research

INTERVIEW

Ms. POONAM BAGAI
Founder Chairman, CanKids...KidsCan
Vice Chairman Pallium India
ICMR, CECHR Member
CCI WHO SEAR Representative
Cancer Survivor
Patient Advocate I Philanthropist

■ **GOVERNMENT PERSPECTIVE**
Understanding India's Drug Safety and Clinical Research System

PLUS DESKTALK • OUT OF THE BOX • AFTERWORD

Late Mr. Narindra Nath,
Founder, Hindustan Syringes and Medical Devices Ltd.

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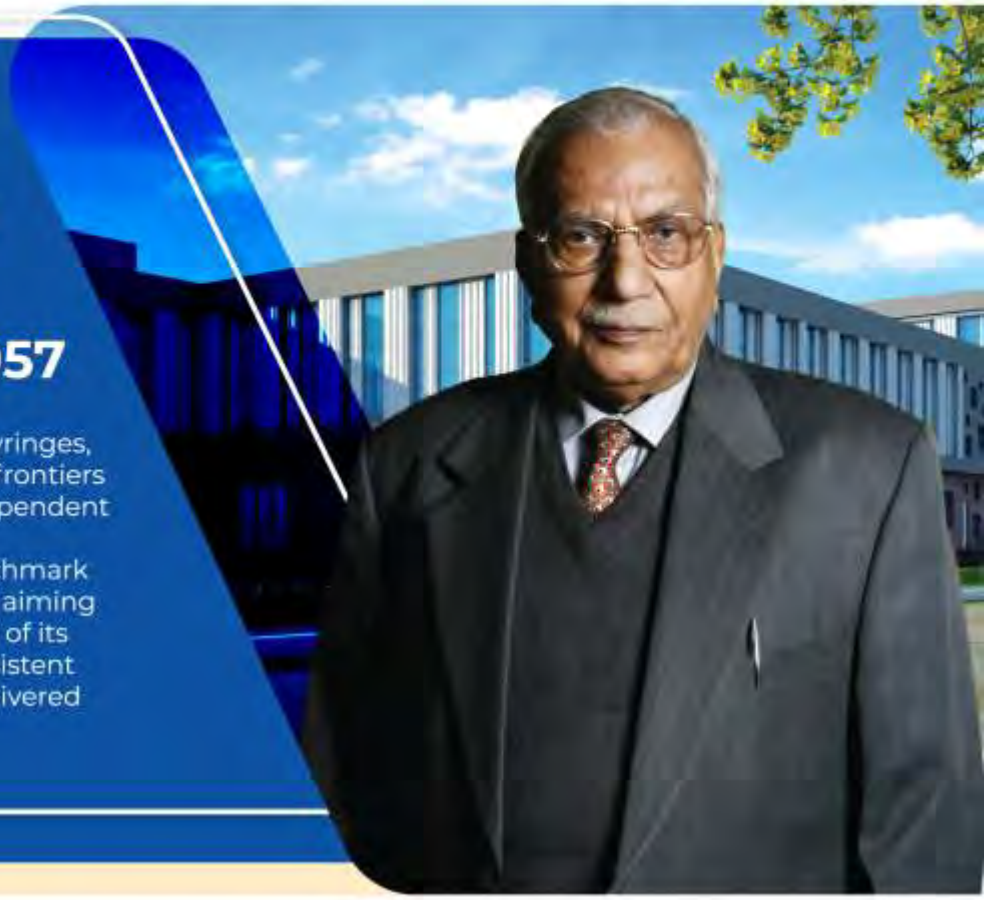

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VIEW POINT

MESSAGE FROM PUBLISHER & EDITOR

Patients as Consumers: A Missing Lens in CLINICAL RESEARCH

CLINICAL RESEARCH IS meant to be the engine of medical progress. It is where new drugs are tested, therapies are refined and hope for better outcomes is born. Yet, along this journey, the patient has been defined, tightly regulated and quietly positioned - not as a consumer of care, but as a 'subject' in a system driven by protocols.

For patients facing high out-of-pocket expenditure or limited treatment pathways, clinical research can represent both opportunity and uncertainty. The economic burden of care, combined with unequal access to innovative therapies, further complicates the experience. In such a scenario, clinical research is not just scientific - it is closely linked to access, affordability and survival options.

Within this context, a critical gap emerges. Patients in clinical research are not only recipients of interventions; they are also stakeholders who invest trust, time and emotional as well as physical resilience during the process. Yet, their role is rarely framed through rights, choice and consumer-like agency.

Recognising patients as consumers within clinical research does not diminish scientific integrity. Instead, it strengthens the ecosystem by emphasising transparency, accessibility, affordability and equitable participation.

What does it really mean for a patient when access to care depends not only on medical need, but also on affordability and availability of treatment options?

This shift also opens space for patient advocacy groups (PAGs), extending their role beyond support and navigation to actively shaping awareness, understanding treatment pathways and ensuring research aligns with real-world patient needs - especially where cost and access remain major barriers.

As clinical research evolves, the focus must move beyond participation alone. It must include access, affordability and accountability - ensuring patients are not only part of the system, but meaningfully empowered within it.

Here, it is initiatives like Patient Advocates for Clinical Research (PACER) that are promoting participation in clinical research by helping patients understand complex trial information in simple language, building their confidence to ask questions and empowering them to become 'active partners' who can represent the patient voice in clinical research.

Afterall, research will become stronger, fairer and kinder when patients lead the way!

Prof. Bejon Kumar Misra
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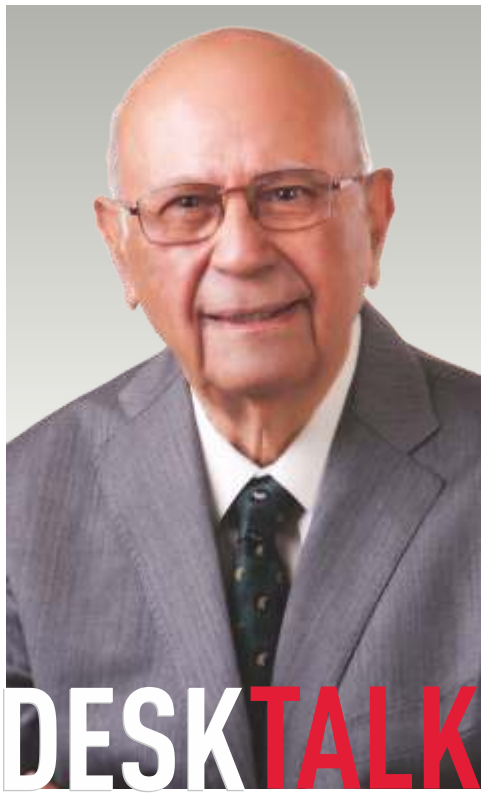

DESKTALK

POWERING A PATIENT-CENTRIC CLINICAL RESEARCH ECOSYSTEM

CLINICAL TRIALS ARE primarily viewed through a scientific lens - defined by protocols, phases and outcomes. While vital to medical progress, at their core, clinical trials hinge on one fundamental reality: **patient participation**.

As the very foundation of clinical research, the patients are also consumers - of information, of care and of trust. And like any consumer, they are entitled to clarity, dignity, safety and choice.

Yet, the lived experience tells a different story. Too often, patients enter clinical trials feeling uncertain, overwhelmed and underinformed - rather than empowered and respected.

The issue here is that clinical trials are deemed as experimental, unproven, risky and distant from everyday clinical care. They are rarely presented as a standard treatment pathway; always positioned as a **last resort** - something patients turn to only when all else fails. In moments of vulnerability, this transforms participation from a considered decision to an act of desperation.

This is not just a communication gap - it is a systemic failure.

At a time when medical innovation is advancing rapidly, there is an urgent need to reframe clinical trials as patient-centric, ethical and viable treatment options - and to build awareness of this shift among researchers, healthcare providers and patients alike.

Doctors often hesitate to suggest trials due to time constraints, lack of information and concern about patient reactions. They should consider clinical trials as an integrated treatment option rather than just a fallback.

On their part, the clinical researchers need to rise above the clinical metrics and view patients as active participants (read: partners) rather than just passive subjects (read: guinea pigs)! Patient convenience should shape the study and their feedback should guide the path ahead. Accountability and transparency will come in when the patients are fully informed about the risks, benefits and progress. Maintaining open communication, privacy and confidentiality is equally crucial.

The most critical shift is needed at the patient level. Clinical trials should not be seen as a blind leap of faith, but a legitimate and informed choice in the treatment journey. They can provide access to cutting-edge treatments, that are not yet widely available, with possibility of better outcomes.

Clinical trials are the bridge between today's treatments and tomorrow's cures. But, that bridge is only as strong as the trust and awareness that support it!

INSIDE

REGULARS

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Obtuse Angle by Prof. B P Acharya

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UNLOCKING CONSUMER POTENTIAL
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CLINICAL RESEARCH IN INDIA:

Safety, Trust and the Growing Voice of Patients

IN APRIL 2002, *Time Magazine* carried a striking warning — patients in clinical trials were being seen as 'human guinea pigs'.

For many people, that fear stayed alive for years.

Even today, when patients hear the words *clinical trial* or *clinical research*, the first reaction is often hesitation:

Will I be safe?
Can I trust the system?
Will my rights be protected?

These concerns are understandable. Health decisions are deeply personal, especially for families already coping with illness, uncertainty and financial stress.

The principles of informed consent and medical negligence often become blurred under layers of complexity and scientific framing involved in clinical trials.

For instance, consent is frequently treated as a procedural requirement —documented, filed and checked off. But, true informed consent is not about paperwork; it is about **understanding**.

Patients must be able to clearly comprehend:

- The nature and purpose of the trial
- Potential risks and uncertain outcomes
- Available alternatives, including standard treatments
- Their right to refuse or withdraw without any penalty

However, long, technical consent forms and time-pressured discussions often reduce this process to a formality. For patients already under emotional and physical stress, this creates a dangerous illusion of choice.

Then again, while trials are governed by protocols and ethical oversight, lapses can and do occur:

- Inadequate disclosure of risks
- Poor monitoring of adverse events
- Delays in reporting or responding to complications
- Deviations from approved protocols

For years, clinical trials were seen as distant from mainstream care: highly technical, poorly understood and associated more with experimentation than patient welfare. Participation was often viewed as a desperate last step rather than an informed treatment choice.

When such failures lead to harm, they cannot be dismissed as unfortunate side effects of experimentation. Patients in clinical trials are not assuming unlimited risk. Their participation is conditional upon the assurance that:

- Every possible safeguard is in place
- Any harm will be promptly addressed
- Accountability mechanisms will be enforced

Patients do not waive their rights when they enter a trial. If anything, it intensifies the responsibility of those conducting it!

Slow But Significant Transformation

Over the last two decades, the narrative of clinical research has been steadily changing.

Today, clinical trials are no longer viewed simply as experiments — they are highly regulated scientific processes with multiple built-in safety checks designed to protect participants at every stage. From ethics committee approvals and informed consent to medical monitoring and adverse event reporting, patient safety has become central to how modern clinical research operates.

India, too, is undergoing a major transformation.

As the country positions itself as a growing global leader in healthcare innovation, biotechnology, vaccines, digital health and affordable medical solutions, stronger regulations and structured oversight systems have become essential priorities.

And perhaps, for the first time, patients themselves are beginning to shape the future of research in India.

"Inclusive clinical research is possible only when patients are involved not just as participants, but as contributors shaping study design, communication, and ethical safeguards."

DR. HARESH GUPTA
Deputy CEO, CanKids KidsCan
Patient Advocate, Team PACER

So… How Are Patients Protected?

One of the biggest misconceptions surrounding clinical trials is that patients are left unprotected during studies. The reality is very different.

In India, clinical trials are overseen by the Central Drugs Standard Control Organisation (CDSCO) and registered on the Clinical Trials

If a patient does not fully understand what they are agreeing to, consent cannot be considered truly informed.
A patient-centric ecosystem must, therefore, treat consent as an ongoing conversation, not a one-time transaction.

Clinical research in India is now increasingly focused on ethics, transparency, accountability and patient-centric practices.

The result? **A slow but important shift:**

From patients being seen as passive 'subjects'... to becoming informed participants and active voices in healthcare innovation.

Registry – India (CTRI), improving transparency and public accountability.

Before a single patient enters a study:

- Researchers obtain scientific approvals
- Ethics committees review whether the study is ethical and necessary
- Regulators evaluate whether participant safety measures are adequate

And perhaps, most importantly:

Participation is always voluntary.

Patients have the right to:

- ✔ Ask questions
- ✔ Understand possible risks and benefits
- ✔ Discuss concerns with doctors and family
- ✔ Withdraw from the study at any stage, if they wish to do so

Safety monitoring also continues throughout the trial process.

Doctors, ethics committees, sponsors and regulators closely monitor side effects or unexpected reactions. Every serious adverse event must be reported and reviewed promptly to ensure patient welfare remains the highest priority.

India's research ecosystem has also become more structured and vigilant over the years. Earlier ethical concerns pushed the system towards stronger safeguards, better oversight mechanisms and greater accountability.

For patients, this means that clinical research today operates on a far stronger foundation of ethics and safety than before.

Patients Are No Longer Silent Participants

Something important is changing in healthcare.

Patients today are more informed, more connected and more willing to ask questions about their treatment choices than the previous generations.

Across India, growing awareness about healthcare rights, easier digital access to information and the work of patient advocacy groups are encouraging more people to actively engage in conversations around clinical research.

But, participation is not only about signing a consent form.

Patients are increasingly being recognised as essential voices in healthcare innovation.

Because researchers may understand diseases scientifically — but patients understand what it feels like to *live* with them every day.

> **"Clinical trials are safe as the government has created ethical, scientific and regulatory processes to ensure safety and patient protection."**

DR. SAMEER BAKHSHI
Professor, Department of Medical Oncology, All India Institute of Medical Sciences, New Delhi

They understand:

- What treatment challenges affect daily life
- Which side effects truly matter
- What financial burdens families struggle with
- What 'better quality of life' actually means in reality

This shift towards patient-centric research is changing how studies are designed and discussed.

Patient Advocacy Groups (PAGs) are also helping bridge the communication gap by:

- Simplifying complex research information
- Supporting informed decision-making
- Creating dialogue between communities and healthcare professionals

India's Research Ecosystem Is Expanding

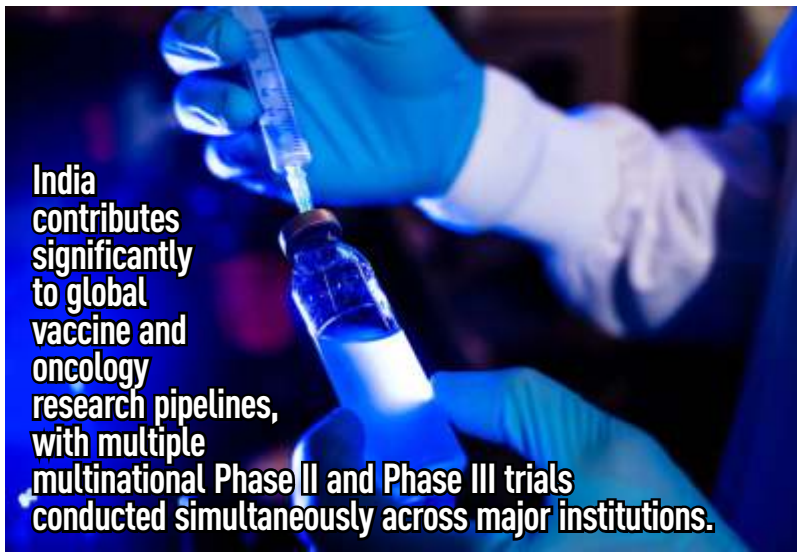
Clinical research does not function in isolation. It is supported by a complex ecosystem involving hospitals, investigators, ethics committees, pharmaceutical companies, contract research organisations (CROs), regulators and **patients**.

India's research ecosystem has expanded significantly over the last decade, but it continues to face structural challenges:

- Uneven distribution of research infrastructure beyond metro cities
- Limited trained clinical research professionals in some regions
- Variability in trial awareness among healthcare providers
- Administrative and operational delays in trial initiation

"Building awareness about the role of clinical trials in evidence generation through culturally relevant Good Participation Practices is essential to fostering ethical, inclusive and trusted research that empowers communities and strengthens public confidence in clinical research."

Mr. ANIRBAN ROY CHOWDHURY
Associate Vice President, Sun Pharma;
General Secretary,
Indian Society for Clinical Research



"सुरक्षित औषधि, सशक्त राष्ट्र — PvPI राष्ट्र के औषधि प्रहरी"

DR JAMAL BAIG
Director, Drug Safety,
APAC Head, MSD India

Despite this, India remains an attractive destination for global and local research due to its:

- Large and diverse patient population
- Skilled medical professionals
- Cost-effective research environment
- Growing regulatory maturity

Leading academic hospitals and cancer centres are now actively participating in multinational clinical trials, while domestic innovation is also increasing.

The ecosystem is gradually moving towards a more structured, quality-driven model where training, standardisation and patient engagement are becoming central priorities.

Because, ultimately, clinical research is not only about developing treatments — it is about improving lives.

Clinical Trials Tell One Story. Real Life Tells Another

Imagine this:

A medicine performs extremely well during a clinical trial.

But, what happens after it reaches the real world?

"We navigated clinical trials and landed on a suitable one almost by chance. Better info, better access would pave the way for effective, gentler treatments."

Ms. KANAKAPRIYA
Parent of Clinical trial Participant

DR. AMITA MAHAJAN
Senior Consultant and Clinical Lead
Paediatric Hematology-Oncology Service,
Indraprastha Apollo Hospitals (New Delhi)

Clinical Trials as a Care Option: Moving Beyond Fear Towards Hope

Today, experts around the world are promoting the idea of **Clinical Research as a Care Option (CRAACO)** — a patient-centred approach that sees clinical trials not as a 'last resort', but as another possible pathway of care for eligible patients.

The CRAACO approach recognises that clinical trials can sometimes offer patients early access to innovative treatments, expert medical supervision and closer health monitoring. For patients with serious or chronic illnesses, this may provide opportunities that are not yet widely available through standard treatment pathways.

While clinical trials answer "Can this treatment work?", real-world evidence answers "Does it work for everyone, everywhere?"

What about patients who are:

- Balancing work and caregiving
- Struggling financially
- Managing multiple illnesses
- Missing follow-up visits
- Living far from healthcare facilities

This is where **Real-World Evidence (RWE)** becomes important.

Trials = Controlled Environment

RWE = Real Hospital + Real Patients + Real Conditions

In a country as diverse as India, this becomes especially valuable.

Because healthcare outcomes are influenced not only by medicines — but also by affordability, access, lifestyle, awareness and social conditions.

Together, both forms of evidence create a more complete understanding of healthcare interventions.

The Patient as Consumer

The phrase 'Patient as Consumer' reflects a major transformation in healthcare culture. A generation ago, patients often relied completely on doctors to make decisions on their behalf, rarely questioning diagnoses or treatments. Today, however, the healthcare landscape has evolved significantly. With medical knowledge now easily accessible, patients explore information about diseases online, evaluate different treatment options, ask questions about possible side effects and actively seek second opinions before making important healthcare decisions.

Yet, the idea of the 'Patient as Consumer' does not mean healthcare should become commercialised. Rather, it highlights the growing importance of patient-centred care — a system where patients are informed, respected and involved in their own health journey. Modern patients deserve clear information about their conditions, transparency in treatments and costs, respect for their choices, participation in decision-making, and above all, safe and quality care.

This evolving relationship between doctors and patients is reshaping healthcare into a partnership built on trust, communication and shared responsibility. When patients are empowered to take an active role in their care, healthcare becomes not only more effective, but also more compassionate.

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FROM AWARENESS » TO ACTION

Patients are driving the need for patient centric-research. Today, they should play an active role in priority setting exercise and should be a partner in the Data Quality And Data Safety (DPDP Act 2026)

WITHOUT INFORMED PATIENTS, caregivers, clinicians and researchers working together, even the strongest research systems struggle to create meaningful patient impact.

Hence, the larger mission is not only to improve awareness about clinical trials — but to build trust, participation, dialogue and a more patient-centred culture of research in India.

Patients Driving the Need for Patient-Centric Research

Patients today are changing the way healthcare and clinical research are viewed. Earlier, most patients simply followed treatment decisions made for them. But now, many patients and caregivers want to understand more about their illness, available treatment options and how research decisions affect their lives.

They are asking important questions:

- Why are some treatments available in other countries, but not easily accessible here?
- Why are certain patients included in clinical trials while others are not?
- How are research studies designed?
- Are patient concerns and daily challenges really being considered?

This growing awareness is changing clinical research itself.

Doctors and researchers may understand a disease medically, but patients understand what it feels like to live with that disease every day. They understand:

- Treatment fatigue
- Financial stress
- Travel difficulties
- Emotional burden
- Caregiver challenges
- Impact illness has on family life and work

These experiences matter because they help researchers understand whether treatments are practical and meaningful in real life.

When patients are included in discussions around research design and trial experiences:

- Studies become more practical
- Communication improves
- Trust becomes stronger
- Research outcomes become more relevant to real patient needs

Today, patients are not only participating in studies — they are helping shape what patient-centred research should look like.

Patient-centric research is no longer just an ideal concept. Patients themselves are driving the demand for research systems that are more transparent, inclusive, accessible and compassionate.

Patients in Priority Setting: Redefining Research Agendas

One of the most transformative shifts in contemporary clinical research is the growing inclusion of patients in priority-setting exercises. This marks a departure from traditional models where research agendas were largely shaped by institutional and systemic drivers rather than end-user needs.

Historically, the direction of medical research has been influenced by:

- **Industry pipelines,** where therapeutic areas are prioritised based on market potential and innovation feasibility.
- **Academic interests,** where research questions often emerge from scientific curiosity or disciplinary advancement.
- **Regulatory frameworks,** which define acceptability and compliance standards, but do not necessarily reflect patient lived realities.

While each of these systems plays an important role in maintaining scientific rigor and innovation, they do not consistently capture what matters most to patients and caregivers who experience illness in everyday life.

This gap becomes especially evident when clinical and patient priorities diverge. For instance, patients may value:

For most patients, quality of life matters just as much as medical outcomes. A treatment may appear successful scientifically, but if it causes severe side effects, repeated hospital visits or major financial strain, patients may experience it very differently. This is why patient involvement is becoming increasingly important in clinical research.

- **Quality of life over marginal survival gains,** especially when extended survival comes with significant toxicity or functional decline.
- **Symptom relief over surrogate or complex clinical endpoints,** such as biomarker changes that do not translate into felt improvement.
- **Access and affordability over technological innovation,** particularly in contexts where advanced therapies may be unavailable or financially unsustainable.

Such differences highlight a fundamental limitation of traditional priority-setting approaches: they often optimise for scientific advancement without fully integrating lived experience. Global evidence strongly supports the integration of patient voices in research prioritisation.

In the Indian context, the importance of this shift becomes even more pronounced. Healthcare delivery is marked by significant variability in:

- Geographic access to specialised care
- Socioeconomic ability to afford treatment continuity
- Infrastructure differences between urban tertiary centres and rural or semi-urban facilities

As a result, what is considered 'feasible' in research design may not always reflect what is feasible in real-life care pathways. Trials designed without patient input risk becoming misaligned with the realities of treatment access, adherence and follow-up in diverse Indian settings.

Involving patients in priority setting directly addresses this gap by:

- Making research more inclusive, ensuring that diverse lived experiences — especially from underserved populations — are represented in shaping research questions.
- Amplifying marginalised voices, including caregivers, rural patients and those navigating financial and logistical barriers to care.
- Improving the actionability of outcomes, so that research outputs can be realistically implemented within existing healthcare systems.

This shift is changing the relationship between patients and researchers. Clinical research is gradually moving from: 'research on patients' to 'research with patients'.

And that creates healthcare systems that are not only scientifically strong, but also more compassionate and meaningful for the people they serve.

Patients as Partners in Data Quality and Data Safety

As healthcare becomes more digital, patients are becoming increasingly aware that their medical information is valuable — and that it must be protected responsibly.

Today, health data is collected through:

- Hospital records
- Laboratory reports
- Mobile health applications
- Wearable devices
- Insurance systems
- Clinical research studies

"Patients deserve respect, privacy, safety, and complete transparency throughout clinical research, with the freedom to ask questions or withdraw at any stage. Nothing about me, without me!!."

Mr. NIRBHAY SINGH
Head, Parent and Survivor Group, CanKids KidsCan
Patient Advocate, Team PACER

This information helps improve healthcare planning, research and treatment development. But, it also raises important questions for patients:

- Who can access my health information?
- How is my data being used?
- Is my privacy protected?
- Can my information be shared without my knowledge?

India's evolving Digital Personal Data Protection (DPDP) framework reflects a growing recognition that patients should have greater awareness and control over their personal data.

Patients are no longer seen simply as providers of data. They are becoming active stakeholders in decisions related to how health information is collected, stored, shared and protected.

However, challenges still remain. Many people are still unaware of their data rights while concerns around misuse of personal information continue to grow, especially in the age of artificial intelligence and digital healthcare platforms.

This is why patient awareness and engagement are essential.

Trust in healthcare systems becomes stronger when patients feel informed, respected and included in conversations about their own data.

In the DPDP era, data is no longer a one-way extraction. It is a shared responsibility — and patients are central to it.

Patients as Partners in Capacity Building

As healthcare systems increasingly talk about 'patient-centric research', an important question also needs to be asked:

How do we know whether a clinical research practice is truly patient-friendly?

A hospital or research unit may follow scientific protocols correctly, but patients often experience healthcare differently. What matters to patients is not only the treatment itself, but also:

- How clearly information is explained
- Whether their concerns are heard
- How respectfully they are treated
- Whether consent processes are understandable
- Whether the overall environment feels supportive and trustworthy

When patient advocates participate in evaluating research centres and training programs, they help bring attention to areas that may otherwise be overlooked, such as:

- Emotional support
- Communication gaps
- Patient comfort
- Practical difficulties during visits
- Clarity of information provided during trials

This creates a more balanced and compassionate approach to clinical research.

Behind every data point is a real person, a real experience and a real story. India's Digital Personal Data Protection Act (DPDP Act) marks a significant transition toward a rights-based data ecosystem. It places patients at the centre of data ownership and control.

This is where the OSKE-R approach becomes important.

OSKE-R (Objective Structured Knowledge Examination for Research) is designed as a patient-centred assessment approach where trained patients and patient advocates help evaluate whether clinical research centres, researchers and training systems are genuinely patient-centric.

The idea behind this model is simple but powerful: patients themselves are often best placed to identify whether a system truly understands patient needs.

Through this approach, trained patient advocates become active contributors in evaluating how patient-centred a research system truly is.

Importantly, the focus is not on criticism, but on improvement.

The OSKE-R model encourages research centres and healthcare professionals to better understand patient expectations and improve the overall clinical trial experience. It also highlights an important shift happening in healthcare today: patients are no longer only recipients of care — they are becoming partners in improving the quality of healthcare systems themselves.

Healthcare research is often shaped by the interests of clinicians, researchers and industry, while the needs and priorities of patients and caregivers may not always be fully represented. Priority Setting Exercises (PSEs) help address this gap by bringing together patients, families, healthcare professionals and researchers to identify the most important unanswered questions in healthcare research.

In 2025, the Indian Paediatric Haematology Oncology Group (INPHOG) and the Indian Childhood Cancer Initiative (ICCI) carried out a national exercise to understand the research priorities most important to children with cancer, survivors, families, caregivers and healthcare providers in India.

DR. RAMANDEEP ARORA
Paediatric Oncologist,
Max Super Speciality Hospital & Director, INPHOG;
Member, Governance Council, ICCI

Patients as Partners in Feedback: Closing the Missing Loop

One of the simplest, yet most important, questions in clinical research is often never asked:

How was your experience?

Patients participating in clinical trials may spend weeks or months attending hospital visits, undergoing tests, following treatment schedules and sharing personal health information. Yet, many are rarely given opportunities to openly discuss what worked well and what challenges they faced.

This missing feedback loop affects both patients and research systems.

Patients may experience:

- Confusion during communication
- Logistical difficulties

The Indian patient and public are no longer silent participants in clinical research — they are emerging as informed and empowered stakeholders, emphasising the critical importance of Patient and Public Involvement (PPI) and standing shoulder to shoulder with doctors, regulators, industry leaders, and research professionals in shaping the future of ethical, transparent and patient-centric healthcare.

रिसर्च में भागीदारी, स्वस्थ भारत की जिम्मेदारी

DR. POOJA SHARMA
CEO, APAR Health;
Patient Advocate & Project Lead, PACER;
Senior Researcher, PCRI, CanKids KidsCan

PACER
PATIENT ADVOCATES FOR CLINICAL RESEARCH
United by CanKids And APAR Health

For many patients and caregivers, clinical trials still feel distant, technical and difficult to navigate. The lack of simple, trustworthy information often creates hesitation, fear and missed opportunities to participate in potentially beneficial research. Patient Advocates for Clinical Research (PACER) was created to change that narrative.

PACER (https://pacercankidsindia.org/) begins where most systems often stop — at the point where awareness must transform into understanding, and understanding into meaningful participation.

A joint initiative of Cankids KidsCan and APAR Health, engaging over 41 PAG (Patient Advocacy Groups), PACER works to simplify clinical research into language that patients, families and communities can actually understand.

Its vision is simple, yet powerful:

- **To create expert patients**
- **To create patient-centric and empathetic researchers**
- **To encourage clinicians to view clinical trials as a clinical care options**

- Emotional stress
- Long waiting times
- Financial burdens
- Other concerns they hesitate to raise during appointments

Without structured feedback systems, these experiences may remain invisible.

Introducing patient feedback mechanisms can help make clinical research more patient-friendly and responsive.

Simple measures, such as patient experience surveys, feedback forms, exit interviews and patient advisory groups, can provide valuable insights into improving clinical trial experiences. More importantly, feedback systems send a powerful message to patients: **Your experience matters!**

Listening to patients helps:

- Improve communication
- Strengthen trust
- Identify operational gaps
- Create more compassionate research environments

Because patient-centric research is not only about enrolling patients into studies.

It is also about listening carefully to the people whose experiences shape the future of healthcare.

"Scientific progress must ultimately serve humanity. Ethical clinical research, strong public health systems, and informed patient participation are essential to building trust, advancing innovation, and ensuring that healthcare reaches every community with equity, safety, and dignity."

Professor NIRMAL KUMAR GANGULY
Former Director General,
Indian Council of Medical Research (ICMR)

Its real strength lies in empowering patients to ask questions, make informed decisions and gradually evolve into 'expert patients' — individuals who can confidently represent the patient voice within the research ecosystem.

PACER is also helping build patient advocates who can:

- Bridge the gap between researchers and communities
- Support other patients in navigating clinical trials
- Contribute towards improving research systems from within

It strongly aligns with the global principles of Patient and Public Involvement (PPI) in research, where patients, caregivers and communities are not viewed merely as study participants, but as active contributors in shaping research priorities, study design, communication strategies and patient engagement approaches.

Internationally, organisations and frameworks such as INVOLVE (UK), Patient-Centered Outcomes Research Institute (PCORI, USA), European Patients' Academy on Therapeutic Innovation (EUPATI), National Institutes of Health (NIH), and World Health Organisation have increasingly emphasised meaningful patient engagement and co-creation within research ecosystems. PPI encourages research systems to move beyond consultation towards meaningful collaboration, ensuring that clinical research becomes more relevant, accessible, ethical and responsive to real patient needs in India.

This shift is especially important in India, where awareness about clinical research remains uneven and access to reliable information is still limited in many communities.

SSii

SSI MANTRA

PROUDLY MADE IN INDIA FOR THE WORLD

SS Innovations International Inc. is a leading medical technology company founded by Dr. Sudhir Srivastava, a globally acclaimed robotic cardiac surgeon. Dr. Srivastava, serving as the founder, chairman, and CEO, has revolutionized the field of cardiothoracic surgery through his pioneering work in robotic procedures. He holds the record for the most number of robotic Beating Heart Totally Endoscopic Coronary Artery Bypass (TECAB) surgeries. His visionary approach led to the development of the groundbreaking surgical robotic system, the SSi Mantra. This innovative technology aims to transform the landscape of robotic surgery by making advanced, affordable, and accessible surgical procedures available to underserved populations worldwide by decentralizing excellence.

Sudhir Srivastava, MD
Founder, Chairman and CEO

Surgeries Completed Worldwide

6257

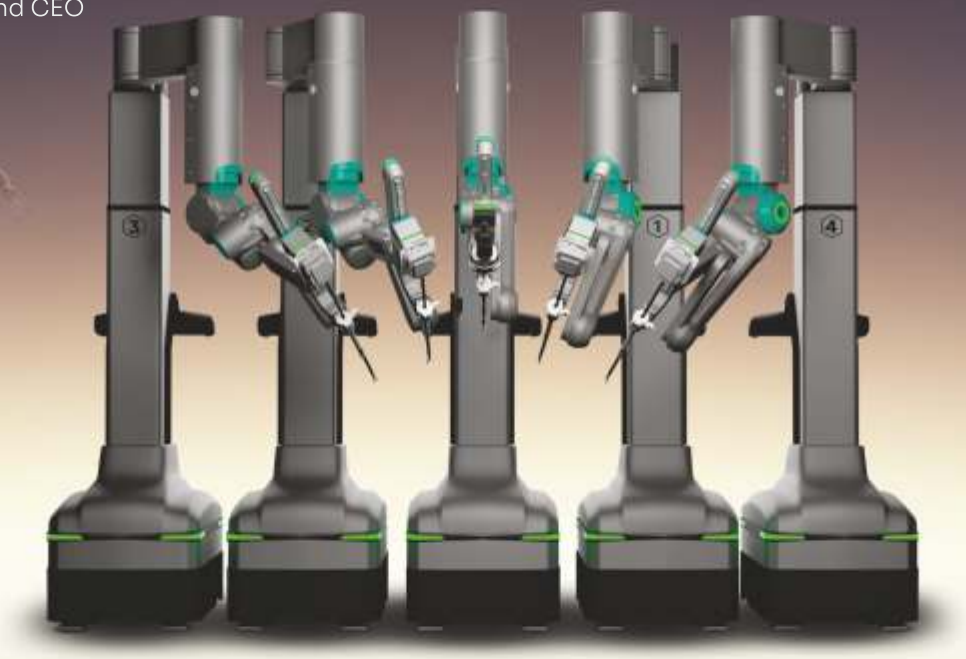
Total Installations Worldwide

125+

Total Telesurgeries Performed

70

(Data as of Mid of Oct 2025)



The most advanced surgical robotic system, offering innovative features and multi-specialty surgical capability, including robotic cardiac surgery. With user-friendly interfaces and exceptional quality and performance, SSI Mantra decentralizes and democratizes robotic surgery.

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UNDERSTANDING INDIA'S DRUG SAFETY AND CLINICAL RESEARCH SYSTEM

MOST OF US swallow a tablet, receive an injection or use a medical device without realising the years of research, testing, regulation and monitoring behind it. We rarely think about the government systems designed to protect us from unsafe medicines or unethical research. Yet, these systems quietly work in the background every single day.

Before a Medicine Reaches You

Clinical research is the bridge between scientific discovery and patient care. Without it, modern medicine would not exist. Every vaccine, antibiotic, cancer therapy, insulin injection, heart stent or surgical implant available today has passed through clinical research.

But, who ensures that these products are safe, ethical and effective? Who protects patients participating in research? And who monitors medicines and devices even after they enter the market?

In India, these responsibilities are managed through a growing network of regulatory and safety systems led by national government bodies.

Transparency Through Trial Registration

One of the most important reforms in India's clinical research ecosystem was the establishment of the Clinical Trials Registry - India (CTRI).

Today, before enrolling participants, clinical trials conducted in India are expected to be publicly registered. This allows patients, researchers, doctors and citizens to understand:

- What studies are being conducted
- Who is conducting them
- Which hospitals and institutions are involved
- What diseases or conditions are being studied
- Whether the trial is interventional or observational

For ordinary patients, trial registration means clinical research is becoming more open, traceable and trustworthy.

This transparency is important because it reduces the possibility of hidden or unethical research practices and improves accountability within the research ecosystem.

CDSCO: India's Drug Safety Gatekeeper

At the centre of India's drug regulatory system is the Central Drugs Standard Control Organisation (CDSCO), functioning under the Ministry of Health and Family Welfare, Government of India.

No new drug or regulated medical device can legally enter the Indian market without approval from the CDSCO. Before granting approval, the organisation evaluates extensive scientific evidence, including:

CDSCO's clinical trial guidance documents emphasise that the 'rights, safety and well-being' of trial participants must prevail over the interests of science and society. This language reflects a globally accepted ethical principle — that human dignity cannot be compromised for scientific advancement.

- Safety data
- Manufacturing quality
- Risk-benefit analysis
- Clinical trial results
- Side-effect profiles

The Drugs Controller General of India (DCGI), who heads CDSCO, plays a critical role in approving clinical trials and new medicines.

In many ways, the CDSCO functions as the country's medical gatekeeper — deciding which therapies are safe enough to move from research laboratories into hospitals and pharmacies.

Recent Developments

Over the years, India's regulatory framework has evolved significantly. Concerns once raised about unethical trials, weak oversight and inconsistent standards led to major reforms.

One of the most important developments was the introduction of the *New Drugs and Clinical Trials Rules (NDCTR), 2019*.

These rules strengthened:

- Ethical oversight
- Trial approval systems
- Compensation mechanisms
- Transparency requirements
- Timelines for approvals
- Participant protections

The shift reflected an important realisation: Scientific innovation cannot come at the cost of patient safety.

The New Drugs and Clinical Trials Rules, 2019 emphasised that participants enrolled in clinical trials are entitled to protection not only during the study, but also in situations involving trial-related injury or adverse events. By formalising medical management and compensation mechanisms, the regulations attempted to reinforce public trust in clinical research systems.

Understanding Clinical Research: Drugs and Devices

Clinical research is not limited to medicines alone; it also includes vaccines, diagnostic technologies, surgical implants, cardiac stents, orthopaedic devices, artificial intelligence-enabled medical tools, wearable health technologies and in-vitro diagnostic devices.

Drug development and device development often follow different scientific pathways.

Medicines usually progress through laboratory studies, animal research and phased human clinical trials before approval. Medical devices, however, may require evaluations focused on performance, usability, engineering safety, software reliability, biocompatibility and real-world functionality.

Medical Device Rules and India's Evolving Device Ecosystem

A major regulatory milestone came with the introduction of the Medical Devices Rules (MDR), 2017, which created a more structured framework for regulating medical devices in India.

Traditionally, only a limited number of medical devices were regulated as 'drugs' under Indian law. However, the expanding healthcare technology ecosystem required a dedicated regulatory approach.

The Medical Devices Rules introduced:

- Risk-based classification of devices
- Licensing pathways for manufacturers and importers
- Quality management requirements
- Clinical investigation provisions for devices

> "Every innovation in medical technology should answer one simple question: how does this improve the patient's journey — from diagnosis to recovery? Affordable medical devices are not just an economic advantage; they directly reduce delays in treatment, shorten hospital stays, and improve survival outcomes for patients."

DR JITENDRA SHARMA
MD & CEO, AMTZ

As healthcare technologies become more advanced, India's regulatory systems have also evolved to manage increasingly complex innovations.

- Post-market surveillance systems
- Stronger compliance standards

Over time, India has also moved towards regulating all medical devices under a more comprehensive framework.

This shift has become especially important as India positions itself as a growing hub for medical technology innovation, indigenous device manufacturing, AI-enabled healthcare technologies, affordable healthcare engineering and startup-driven health innovation ecosystems.

As medical technologies become more sophisticated, regulatory systems must evolve equally to ensure patient safety while encouraging innovation.

Institutions such as the Andhra Pradesh MedTech Zone (AMTZ) represent this larger transformation by supporting innovation, manufacturing, testing and medical technology development within India.

Drug Safety Does Not End at Approval

Approval does not mean the end of scrutiny. Even after medicines reach the market, they continue to be monitored through systems of pharmacovigilance — the science of detecting and preventing adverse drug reactions.

The Pharmacovigilance Programme of India (PvPI) - coordinated by the Indian Pharmacopoeia Commission - plays a central role in ensuring that medicines available in the market are safe, effective and used rationally.

PvPI collects reports of side effects from:

- Doctors
- Nurses
- **Patients themselves**
- Pharmacists
- Hospitals

This is one of the most significant shifts in modern healthcare — patients are increasingly recognised as contributors to drug safety monitoring.

If unusual patterns emerge, authorities may:

- Issue warnings
- Restrict usage
- Update safety labels
- Withdraw medicines from the market

Drug safety, or pharmacovigilance, is an essential component of modern healthcare systems. In a country as large, diverse and with global influence as India, monitoring the safety of medicines is both a challenge and a necessity.

India's regulatory framework mandates that every serious adverse event during a clinical trial is reported within 24 hours, rigorously reviewed by Ethics Committees and regulatory authorities, and assessed for compensation where applicable — ensuring transparency and accountability in patient safety.

PvPI ensures that drug safety continues even after a medicine reaches the market

In other words, monitoring and regulation continue long beyond clinical trials and entry of the drugs into the market.

In recent years, PvPI has expanded its scope to include monitoring of vaccines, medical devices and herbal medicines. This expansion reflects the evolving landscape of healthcare and acknowledges the widespread use of alternative therapies in India. The COVID-19 pandemic, for example, highlighted the importance of vaccine safety surveillance, and PvPI played a key role in monitoring adverse events following immunisation (AEFI).

Capacity building and awareness are also core components of PvPI. Regular training programmes, workshops and educational initiatives are conducted to sensitise healthcare professionals about the importance of ADR reporting.

Despite progress, under-reporting remains a challenge, often due to lack of awareness, time constraints or perceived uncertainty about causality. Strengthening reporting culture is crucial for improving the quality and quantity of safety data.

An analysis of Clinical Trials Registry – India (CTRI) data found that nearly half (49.5%) of Phase IV clinical studies in India have been successfully completed, reflecting ongoing post-marketing safety and effectiveness monitoring.

The Pharmaco-vigilance Programme of India (PvPI) also marked an important cultural shift by encouraging patients themselves to report adverse drug reactions. Traditionally, drug safety systems depended largely on doctors and hospitals. The newer framework recognised patients as active contributors to medicine safety surveillance.

In conclusion, PvPI has significantly strengthened the framework of drug safety in India over the past decade. By fostering a culture of vigilance, encouraging stakeholder participation and integrating with global systems, PvPI contributes to safer healthcare outcomes. Continued efforts in awareness, digital innovation and regulatory responsiveness will further enhance India's pharmacovigilance ecosystem and protect patient well-being.

Pharmacovigilance Programme of India (PvPI) and Drug Safety: Strengthening Public Health

PvPI was launched by the Ministry of Health and Family Welfare, Government of India, in 2010, with the Indian Pharmacopoeia Commission (IPC), Ghaziabad, serving as the National Coordination Centre (NCC). The programme aligns with global pharmacovigilance standards and contributes data to the WHO Programme for International Drug Monitoring (PIDM), coordinated by the Uppsala Monitoring Centre (UMC), Sweden. Its primary objective is to safeguard patient health by detecting, assessing, understanding and preventing adverse drug reactions (ADRs).

One of the key strengths of PvPI is its 1000+ network of Adverse Drug Reaction Monitoring Centres (AMCs) across medical colleges, hospitals and healthcare institutions in India. These centres actively collect ADR reports from healthcare professionals, including doctors, pharmacists and nurses, as well as directly from patients. The collected data is carefully reviewed and entered into a national database, which is further shared with global systems to enhance drug safety surveillance worldwide.

The reporting of ADRs is voluntary, but strongly encouraged. PvPI has simplified the reporting process by offering multiple channels, such as paper-based forms, a toll-free helpline (1800-180-3024) and a mobile application. The introduction of consumer reporting has been a significant step, empowering patients to participate directly in pharmacovigilance activities. This inclusive approach helps capture real-world data and improves signal detection.

Signal detection is a critical function of PvPI. By analysing patterns in reported ADRs, the programme identifies potential safety concerns associated with medicines. These signals are evaluated by expert committees, and, if necessary, regulatory actions are recommended. Such actions may include updating drug labels, issuing safety alerts, restricting usage or even withdrawing a drug from the market (in rare cases). This continuous monitoring ensures that the benefit-risk profile of medicines remains favourable.

> "The strength of clinical research lies in its collective responsibility: a system where science, ethics, law, and patient voices come together to ensure safety, transparency, and trust at every step of a clinical trial."

DR. PADAM SINGH
Chief Statistical Adviser, Medanta Institute of Education and Research, Gurugram
Former Additional Director General, ICMR

Materiovigilance: Monitoring Medical Device Safety

As the use of medical devices grows rapidly, India has also expanded its focus beyond medicines towards device safety monitoring through materiovigilance. The **Materiovigilance Programme of India (MvPI)** was established to monitor adverse events associated with medical devices.

This includes issues related to:

- Device malfunction
- Incorrect readings
- Mechanical defects
- Diagnostic inaccuracies
- Software failure
- Implant complications
- User safety concerns

Materiovigilance helps identify patterns of device-related problems and supports early safety detection, regulatory action, product recalls when necessary, improved manufacturing quality and stronger patient protection systems.

> Medical devices can directly influence patient outcomes - even small technical failures may lead to serious consequences.

As India's medical technology ecosystem expands, materiovigilance is becoming increasingly important in ensuring that innovation remains safe, ethical and accountable.

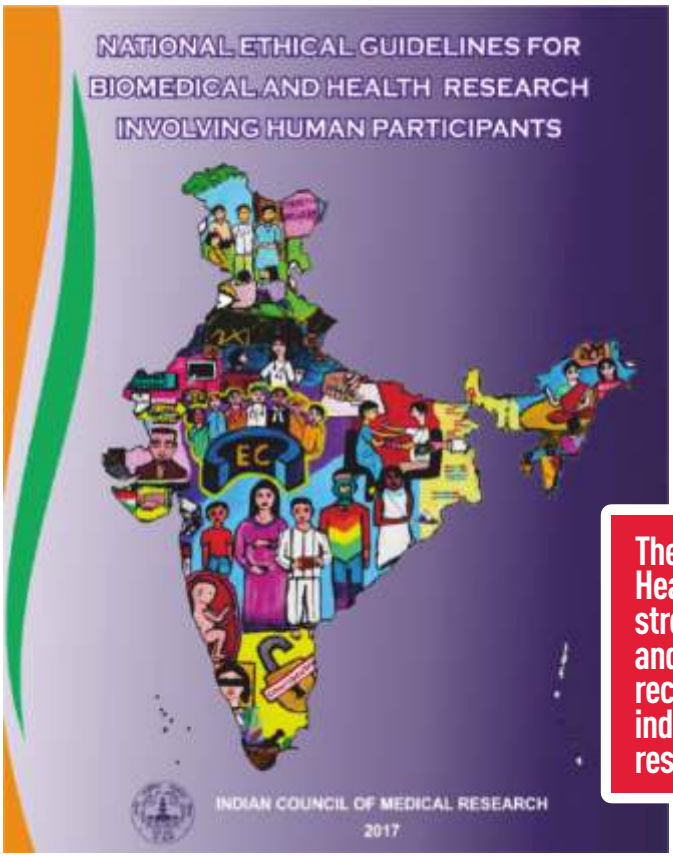
> "Patient safety does not end with drug approval — it begins there. A robust pharmacovigilance system empowers patients, strengthens public trust and ensures that every clinical advancement remains accountable to the people it serves."

DR. Y K GUPTA
Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP); President, AIIMS – Kalyani; Former President of AIIMS Bhopal and AIIMS Jammu; National Scientific Co-Ordinator, Pharmacovigilance Program of India (PVPI)

What If Something Goes Wrong?

No medical system is entirely risk-free. Even after multiple phases of testing and regulatory review, unexpected side effects or adverse reactions can still occur. Recognising this reality, India's clinical research regulations have increasingly focused on accountability and participant protection.

Under the New Drugs and Clinical Trials Rules (NDCTR), 2019, participants who suffer trial-related injury are entitled to medical management and, in certain cases, financial compensation. Sponsors and investigators are required to report serious adverse events within defined timelines, allowing regulators to review safety concerns quickly and take appropriate action.



Ethics Committees also play an important role in monitoring ongoing trials. Their responsibility does not end once a study is approved. They continue reviewing safety updates, adverse event reports and participant welfare throughout the trial period.

The broader message from India's evolving regulatory framework is clear — scientific progress must remain accountable to the people it aims to serve.

The 2017 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants placed strong emphasis on autonomy, justice, risk minimisation and participant dignity. Importantly, the guidelines recognised participants not merely as 'subjects', but as individuals whose welfare should remain central to all research activities.

INTERVIEW

Ms. POONAM BAGAI

Founder Chairman, CanKids...KidsCan
Vice Chairman Pallium India | ICMR, CECHR Member
CCI WHO SEAR Representative | Cancer Survivor
Patient Advocate I Philanthropist

Over the last two decades, patient advocacy in India has evolved from being primarily support-driven to becoming an important voice in shaping healthcare systems, policy, and clinical research. Among the leaders of this transformation is Ms. Poonam Bagai — a colon cancer survivor, Founder Chairman of CanKids...KidsCan, and one of India's leading patient advocates in childhood cancer care.

Through CanKids and multi-stakeholder platforms, such as the Indian Childhood Cancer Initiative (ICCi), Fight RB India and PACER, she has worked across India to build patient-centred systems that improve access to care, financial protection, continuity of care, survivorship, and outcomes for children with cancer.

In this interview, she reflects on the growing relationship between patient advocacy and clinical research, and why patients and families must move from being passive participants to active partners in research and healthcare decision-making.

Q What is clinical research and why should patient advocacy groups engage in research?

Clinical research is the process through which we develop evidence to improve healthcare — whether through medicines, diagnostics, treatment protocols, supportive care interventions, survivorship models, or healthcare delivery systems. Ultimately, it is about improving outcomes and quality of life for patients.

Patient advocacy groups should engage in research because patients bring perspectives that science alone cannot provide. Researchers may understand disease biology, but patients and families understand the lived realities of illness — the emotional burden, treatment toxicity, financial stress, interruptions to education or work, survivorship challenges, and the practical barriers to accessing care.

If research is conducted without patient input, it risks becoming scientifically strong but socially disconnected.

Patient advocacy groups help ensure that research remains grounded in what truly matters to patients and families. They improve trust, awareness, participation, and relevance. Most importantly, they help shape research questions that reflect real-world needs.

Q In your experience, what gaps exist between research priorities and patient needs?

One of the biggest gaps is the difference between what systems measure and what patients experience. Researchers may focus on survival endpoints, biomarkers, or technological innovation, while patients and families are often dealing with entirely different concerns.

For example:

- A researcher may focus on improving survival by a few months
- A clinician may focus on protocol completion
- A parent may be asking whether treatment will bankrupt the family
- A child may be worried about returning to school or losing friends

These are not competing priorities — they are complementary realities.

The problem arises when patient priorities, such as quality of life, survivorship, continuity of care, emotional well-being, financial protection, and accessibility, are not systematically integrated into research frameworks.

In low- and middle-income countries (LMIC) like India, these gaps become even more important because access itself remains unequal.

Research must therefore not only ask: "Can we cure the disease?"

But also: "Can patients realistically access and complete treatment, survive with dignity, and thrive after treatment?"

Without patient engagement, we risk generating evidence that may be scientifically rigorous but difficult to apply meaningfully in real-life settings.

At CanKids, we believe patients should not only participate in research — they should help shape the questions research asks.

Q What challenges do you see in integrating patients into research decision-making processes?

There are several important challenges, and many of them are systemic rather than individual.

Power imbalance - Traditionally, research institutions and clinicians have been viewed as the primary decision-makers, while patients are consulted later or only minimally. This creates unequal participation.

Technical and language barriers - Clinical research is often communicated in highly technical language, making meaningful participation difficult for many patients and caregivers.

Lack of institutional frameworks - In many settings, patient involvement still depends on individual researchers rather than structured systems or policies.

Limited awareness - Many patients are unaware that they can contribute to research discussions, advisory processes, ethics conversations, or protocol feedback.

Representation challenges - Not all patient voices are equally represented. Vulnerable populations, rural families, children, and economically disadvantaged communities may remain excluded.

Time and financial burden - Patients and caregivers are already managing treatment, work disruption, travel, and emotional stress. Participating in research discussions can become difficult without support systems.

However, these challenges are not impossible to overcome.

What is needed is a shift from seeing patient engagement as optional to recognising it as essential for ethical and effective healthcare research.

Meaningful integration requires:

- Simpler communication
- Institutionalised patient advisory systems
- Training and capacity building
- Diversity in representation
- Respect for lived experience
- Long-term commitment to partnership

Patients should not merely be consulted occasionally; they should be recognised as stakeholders in the research ecosystem.

Q What are some practical ways to make clinical research more patient-centric?

Patient-centric research is not a slogan — it is a set of deliberate actions and design choices. Practically, this means:

- Involving patients and caregivers early during protocol design
- Including patient-reported outcomes as key endpoints
- Simplifying consent documents and communication materials
- Designing trials that reflect real-world constraints
- Reducing unnecessary hospital visits and travel burden
- Providing psychosocial and navigation support
- Ensuring communication remains empathetic and continuous throughout the research journey

In India and other LMIC settings, patient-centricity must also include:

- Financial protection considerations
- Accessibility across regions
- Shared care and decentralised care models
- Language inclusivity
- Digital and community-based support systems

In paediatric oncology, patient-centricity must include the child, the family, and the long-term survivorship journey.

One important shift is moving from asking: "Can the trial be completed successfully?"

To also asking: "Can families realistically participate without disproportionate hardship?"

The true test of patient-centric research is whether it improves both medical outcomes and lived experiences. Most importantly, researchers should continue asking one simple question throughout the process: "Does this matter to patients and families?" If the answer is unclear, the research design likely needs rethinking.

Q What are the unique challenges faced by children with cancer and their families in clinical research and treatment decision-making?

Childhood cancer is fundamentally different from adult cancer because the patient is a child, but the burden of decision-making falls heavily on parents and caregivers. Families are often navigating:

- Complex treatment decisions
- Long treatment durations
- Financial stress and loss of income
- Travel and accommodation challenges
- Fear of relapse and uncertainty
- Emotional trauma and caregiver fatigue

At the same time, children experience:

- Interrupted education
- Social isolation
- Anxiety and emotional distress
- Long-term side effects
- Difficulty expressing their fears and needs

In clinical research, these challenges become even more sensitive because consent involves parents, clinicians, institutions, and sometimes ethics frameworks — while the child's own voice may remain underrepresented.

This is why paediatric oncology research must move beyond cure rates alone. It must also include:

- Quality of life
- Survivorship outcomes
- Neurocognitive and developmental impact
- Reintegration into school and society
- Psychosocial well-being
- Continuity of care
- Financial protection and access equity

At CanKids, we often say that survival is not the finish line. A child must also be able to survive, thrive, learn, grow, and live with dignity after treatment.

CANKIDS..KIDSCAN National Society for Change for Childhood Cancer in India

Q How do you define the relationship between patient advocacy and clinical research today?

Today, patient advocacy and clinical research are deeply interconnected. Research can no longer function in isolation from patient realities, and advocacy must increasingly engage with evidence, data, and systems thinking.

Traditionally, research was viewed as something done *for* patients, while advocacy focused on helping patients navigate healthcare systems. That distinction is rapidly changing.

Today, advocacy must influence how research is designed, implemented, communicated, and evaluated. Research that does not reflect patient priorities risks missing critical dimensions of care such as quality of life, survivorship, affordability, continuity of care, and psychosocial well-being.

In paediatric oncology especially, patient-centred research must go beyond survival rates alone. We must also ask:

- Can the child return to school?
- Is the family financially protected?
- Is survivorship being supported?
- Are long-term toxicities being monitored?
- Is care accessible closer to home?

At CanKids, we have seen that when patient groups engage early with researchers, healthcare institutions, and policymakers, research becomes more ethical, relevant, feasible, and impactful.

Q What role do patient advocacy groups play in improving clinical research in India?

Patient advocacy groups serve as trusted bridges between researchers, healthcare systems, and communities. In India, where awareness about clinical research is still evolving, advocacy groups play an important role in building trust, improving communication, and helping patients make informed decisions.

Their role includes:

- Improving awareness about clinical trials and research participation
- Helping patients and caregivers understand consent processes
- Reducing myths and fears surrounding research
- Supporting recruitment and retention
- Facilitating communication between families and healthcare teams
- Bringing patient feedback into research design and implementation

Importantly, advocacy groups also help researchers better understand the realities patients face outside hospitals — including travel burden, treatment abandonment risks, financial toxicity, social stigma, and interruptions to education and livelihood.

This is especially critical in childhood cancer, where parents and caregivers become central stakeholders in treatment and research decision-making.

When advocacy groups are involved meaningfully, research becomes more inclusive, patient-centred, and implementable in real-world settings.

Q How important is capacity building for patients and advocacy groups in clinical research?

Capacity building is absolutely essential because meaningful patient engagement cannot happen without knowledge, confidence, and preparedness.

Too often, patient participation in research discussions becomes symbolic rather than substantive because patients and caregivers are not given the tools to engage effectively. Patients and advocacy groups need structured understanding of:

- Basic clinical research concepts
- Consent and ethics processes
- Risk-benefit assessment
- Trial design and endpoints
- Patient rights and responsibilities
- Research communication and interpretation

When patients are trained and informed, they become more confident in asking questions, interpreting information, supporting peers, and participating in decision-making.

This shift is extremely important in India, where awareness about clinical research still remains uneven. Capacity building also improves trust. Informed patients are better able to distinguish ethical research from misinformation or fear-based narratives. Ultimately, patient-centric research requires patient-ready systems and research-ready patient communities.

Q How can clinical research become more child-friendly and family-centred in paediatric cancer care?

For clinical research to truly support children with cancer, it must be designed around the realities of children and families rather than only institutional systems and timelines. Child-friendly research means:

- Using age-appropriate communication
- Simplifying explanations for both parents and children
- Making consent and assent processes more understandable
- Minimising unnecessary hospital visits
- Reducing disruption to school and daily routines
- Providing emotional and psychosocial support throughout treatment

Family-centred research means recognising that caregivers are central stakeholders in paediatric cancer care. Parents often manage:

- Treatment schedules
- Financial planning
- Emotional support
- Accommodation and travel logistics
- Long-term follow-up and survivorship care

Their experiences and feedback therefore become extremely important in research planning and evaluation.

Another critical area is survivorship research.

Today, many children survive cancer but continue to face:

- Learning difficulties
- Growth and developmental challenges
- Neurocognitive impact
- Emotional trauma
- Social stigma
- Long-term health complications

Research must therefore focus not only on cure rates but also on how children live after treatment.

At CanKids, we strongly believe that every child has the right not only to survive cancer, but also to continue learning, growing, and participating fully in life.

A truly patient-centric paediatric oncology system is one where children are heard, families are supported, and outcomes reflect long-term well-being and dignity — not only medical success.

Q How can doctors better understand and discuss clinical trials as a care option with patients?

Doctors play a very important role because they are often the most trusted source of information for patients and families. To discuss clinical trials effectively, doctors must first recognise that communication is as important as

scientific knowledge. Patients are more likely to engage positively when doctors:

- Explain research in simple, non-technical language
- Discuss both benefits and limitations honestly
- Clarify patient rights and consent processes
- Encourage questions without judgment
- Address fears and misconceptions empathetically

Clinical trials should not be presented only as a 'last option'. In many cases, they may offer access to innovation, better monitoring, or newer approaches to care. At the same time, discussions must remain ethical and transparent. Patients should never feel pressured into participation.

In paediatric settings especially, communication must involve both parents and children appropriately, while being sensitive to emotional stress and information overload.

Doctors also benefit when they understand patient realities beyond disease biology — including financial burden, travel constraints, psychosocial concerns, and survivorship priorities.

Ultimately, trust and communication are central to patient-centric research participation.

Q What is the future of patient advocacy in clinical research in India?

The future is very promising, but it will require intentional systems-building and sustained collaboration.

India is witnessing growing patient awareness, digital access to information, stronger advocacy networks, and expanding clinical research ecosystems. This creates an important opportunity to embed patient-centricity more deeply into healthcare and research systems.

I believe the future will involve:

- Structured patient advisory mechanisms
- Greater integration of advocacy groups into research governance
- More focus on equity, accessibility, and affordability
- Increased use of patient-reported outcomes
- Greater emphasis on survivorship and quality of life
- Stronger community engagement and research literacy
- Ethical and transparent communication practices

In paediatric oncology especially, the future must move toward integrated systems that combine:

- Cure
- Care
- Continuity
- Financial protection
- Survivorship
- Psychosocial support

India also has the opportunity to develop models that are relevant for low- and middle-income countries globally.

At CanKids, we have seen that when governments, hospitals, researchers, advocacy groups, survivors, and communities work together, healthcare systems become more responsive and humane.

The future of clinical research cannot be built only around institutions. It must also be built around patients, families, and lived experiences.

Q What message would you give to researchers about working with patient advocates?

My message would be simple: Do not see patients as external to research. Patients are not an 'add-on' to clinical trials or healthcare systems — they are central to them.

Every research question ultimately exists because of a patient need. Every data point represents a human life, a family experience, and a healthcare journey. When researchers engage with patient advocates early and meaningfully:

- Research questions become more relevant
- Communication improves
- Recruitment and retention strengthen
- Ethical challenges reduce
- Trust increases
- Outcomes become more meaningful in real-world settings

Patient advocates bring lived experience, community trust, systems understanding, and long-term perspectives that are often difficult to capture through data alone.

The strongest healthcare systems are those where science and humanity work together.

Research should not only advance medicine — it should also advance dignity, equity, access, and quality of life for patients and families.

And ultimately, patient-centred research is not just better for patients — it leads to better healthcare systems for everyone!

AFTERWORD

Ms. KHUSHBOO SHARMA
Assistant Manager, PCRI, CanKids KidsCan

CLINICAL TRIALS:

Myths, Fears and Facts

FEW AREAS IN healthcare generate as much curiosity, confusion and fear as clinical trials. For many people, the phrase itself immediately raises a number of uncomfortable questions:

Are clinical trials safe?
Are patients treated like 'guinea pigs'?
Are people fully informed before participation?
Can participants leave once enrolled?
Who is accountable if something goes wrong?

These fears are not entirely surprising. Clinical research deals directly with human health, uncertainty and medical experimentation — subjects that naturally create anxiety and mistrust. Public perception has also been shaped over the years by media reports, misinformation, isolated unethical incidents and limited understanding of how modern clinical research actually functions.

Yet, clinical trials remain one of the most important foundations of modern medicine. Every vaccine, antibiotic, insulin injection, cancer therapy, surgical implant or life-saving drug available today exists because people once participated in carefully monitored research studies.

Without clinical trials, medical science would simply stop progressing.

Understanding the difference between myth and reality is therefore essential — not only for patients, but for the society as a whole.

Myth 1: Clinical Trial Participants are Treated Like Guinea Pigs

This remains one of the most common fears associated with clinical research.

In reality, modern clinical trials operate under strict scientific, ethical and regulatory oversight. Before a study begins, it must pass through multiple layers of review involving regulators, ethics committees, scientists and medical experts.

In India, no regulatory clinical trial can proceed without approval from the Central Drugs Standard Control Organisation (CDSCO) and a registered Ethics Committee.

Ethics Committees are specifically responsible for protecting participant rights and welfare. Their role includes reviewing:

- Risks and benefits
- Participant information sheets
- Informed consent procedures
- Safety monitoring systems
- Compensation mechanisms

Modern clinical research frameworks increasingly emphasise that participants are not 'subjects' for experimentation, but individuals with rights, dignity and autonomy.

The language itself is evolving — from 'subjects' to 'participants', and increasingly to 'partners' in research.

Myth 2: Participants are Forced to Continue Once They Join

One of the strongest protections in clinical research is the principle of informed consent.

Before enrolment, participants are informed about:

- Purpose of the study
- Possible side effects
- Potential benefits and risks
- Alternative treatment options
- Right to withdraw at any time

Participation is voluntary – not binding.

A participant can leave a clinical trial without losing access to regular medical care. This right exists throughout the study and cannot legally be denied.

However, the larger issue is whether consent is always truly *informed*. It is being increasingly argued that informed consent should not be treated as a one-time signature, but as an ongoing conversation built on clarity and transparency.

Because consent without understanding is not meaningful consent.

Myth 3: Clinical Trials are Only Done on Poor or Vulnerable People

This perception has existed for years, particularly in developing countries, where concerns around exploitation have historically been raised.

India's regulatory reforms over the past decade have attempted to directly address these concerns through stronger safeguards and accountability mechanisms.

Newer regulations strengthened:

- Ethics committee oversight
- Compensation provisions
- Audio-visual informed consent requirements in some studies
- Adverse event reporting systems
- Participant protection mechanisms

The Indian Council of Medical Research (ICMR) guidelines also specifically emphasise additional safeguards for vulnerable populations, including economically disadvantaged individuals, children, pregnant women and those with limited decision-making capacity.

The goal is clear: participation should be ethical, informed and voluntary — never driven by coercion, misinformation or lack of alternatives.

Myth 4: Clinical Trials are Dangerous Because New Medicines are Untested

A common misunderstanding s that medicines entering clinical trials are completely unknown substances being randomly tested on humans.

In reality, human trials begin only after years of laboratory and pre-clinical research. Before reaching participants, medicines are studied extensively in laboratories and animal models. Researchers first attempt to understand:

- Biological effects
- Toxicity
- Dosage ranges
- Preliminary safety profiles

Only after sufficient pre-clinical evidence do the regulators permit human trials.

Clinical trials themselves are conducted in phases:

- **Early phases** evaluate safety
- **Intermediate phases** study effectiveness and side effects
- **Large-scale studies** compare treatments and monitor outcomes

Additionally, participants are monitored closely during trials, often more carefully than in routine clinical settings.

This does not mean risks do not exist — every medical treatment carries some degree of uncertainty — but, modern clinical research operates within structured scientific and ethical safeguards designed to minimise harm.

Myth 5: Once a Drug is Approved, Nobody Checks it Anymore

Drug approval is not the end of safety monitoring. Even after medicines enter the market, they continue to be monitored through pharmacovigilance systems.

In India, this responsibility is handled by the Pharmacovigilance Programme of India (PvPI). Doctors, pharmacists, hospitals — and even patients themselves — can report adverse drug reactions.

This ongoing monitoring exists because some rare side effects become visible only after large populations begin using a medicine.

Modern drug regulation, therefore, treats safety as a continuous responsibility rather than a one-time approval decision.

Despite stronger safeguards, public mistrust around clinical trials continues largely because awareness remains limited. Many patients still opt for clinical trials only in moments of desperation when conventional treatments fail. Hence, there is a need for clinical trials to be discussed as legitimate treatment pathways earlier in the care journey - not merely as 'last-resort experiments'.

Myth 6: Patients Lose Their Rights Inside Clinical Trials

One of the most dangerous misconceptions is that entering a clinical trial strips the patients of their rights and shields institutions from accountability.

It does not. The same principles that apply to routine healthcare are equally applicable to clinical research.

If researchers:

- Fail to adequately explain risks
- Deviate from approved protocols
- Ignore adverse events
- Provide negligent care

…they will still be held accountable.

Patients participating in research do not surrender their legal or ethical protections. In fact, because clinical trials involve uncertainty, the **responsibility towards participants is even greater.**

The Bigger Reality

Modern medicine advances because patients choose to participate in clinical research.

Every major medical breakthrough once began as a clinical trial. But, scientific progress can only remain sustainable when it is built on public trust, ethical responsibility and respect for patient rights. The real challenge today is not merely scientific advancement - it is ensuring that innovation remains accountable, transparent and patient-centric.

The future of clinical research will ultimately depend not only on new discoveries, but on whether people feel safe enough to participate in them!

JAGO GRAHAK JAGO

Failure to Obtain Consent for Medical Test is Deficiency in Service

IN APRIL 2014, Ms. Shakuntala Devi experienced severe facial pain and sought treatment at Max Super Speciality Hospital. She was advised surgery and as part of the pre-operative assessment, the senior cardiologists recommended a dobutamine stress echocardiography (DSE) test to evaluate her cardiac fitness.

On 12th April, during the procedure conducted by Dr. Amit Rana, she suffered a cardiac arrest, became hypotensive and unresponsive, and was shifted to the ICU. She remained in a vegetative state for nearly a month before being moved to a hospital in Rishikesh, where she passed away on 13th May, 2014.

The distraught son, Mr Sandeep Gupta filed a complaint of medical negligence with the Uttarakhand Consumer Disputes Redressal Commission (SC/5/CC12/2014) alleging:

- Administration of peak drug doses without adequate monitoring
- Failure to take necessary precautions during the procedure
- Lack of disclosure of associated risks
- Consent obtained as a mere formality - not truly informed

He further argued that despite being a super speciality hospital, the 'doctor's conduct fell below the standard of a reasonably competent medical practitioner and that the hospital lacked essential equipment to effectively handle the emergency that arose'.

Another contention was misrepresentation of treatment costs - while the hospital initially quoted ₹1,65,000, the family received a bill of ₹5,61,000 which had to be paid before discharge.

The hospital and its doctors, on their part, summarily denied all allegations, maintaining that due protocol and consent procedures had been followed.

While this case arose from a diagnostic procedure, its implications extend directly to clinical research. If failure to obtain informed consent for a medical test constitutes deficiency in service, the threshold for consent in clinical trials must be even higher.

Yet, in reality:

- **Consent forms in trials are often longer, more complex and harder to understand**
- **Patients are frequently under greater emotional distress**
- **The uncertainty and risks are inherently higher**

Consent Not a Checkbox or Formality - it is a Violation of Patient Rights

The Uttarakhand Consumer Disputes Redressal Commission focused on the key issue of negligence in medical care and held that there was complete absence of proof of informed consent.

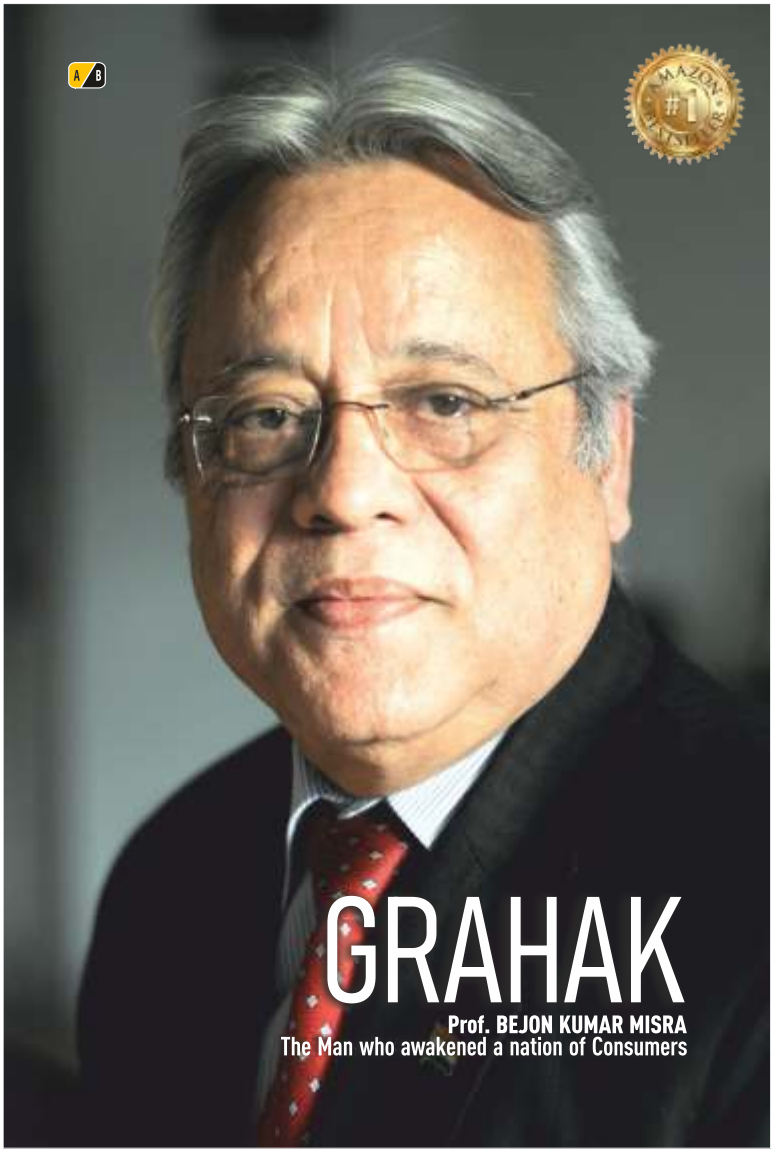
In November, 2025, the bench led by President Ms. Kumkum Rani and Member Mr. C.M. Singh, partly allowed the complaint and ruled that both the hospital and the treating doctor were jointly and severally liable for medical negligence and deficiency in service. They were directed to pay ₹10 lakh in compensation and ₹50,000 as litigation costs to the patient's family, along with 6% simple interest from the date of institution of the complaint until the date of actual payment.

Patient rights cannot end at the threshold of research – they must guide every step within!

GRAHAK

The Man who awakened a nation of Consumers

ग्राहक
अब हिंदी में भी उपलब्ध है।



Grahak' chronicles the remarkable evolution of India's consumer protection movement through the personal lens of one of its founding pioneers. Beginning with telephone connection frustrations in 1980s Jamshedpur, India, the book reveals how everyday grievances sparked a nationwide movement that fundamentally reshaped India's economic landscape.

Prof. Misra's journey from local activism to national policy architect provides unique insights into landmark legislation and regulations, including the Consumer Protection Act of 1986 and 2019. Readers gain unprecedented access to behind-the-scenes accounts of meetings with Prime Ministers Rajiv Gandhi, H. D. Deve Gowda, and Inder Kumar Gujral, the development of the iconic Jago Grahak Jago' multi-media campaign, and the establishment of crucial consumer protection institutions.

Buy Now!

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WATCH OUT

Watch out for the next issue in July 2026 dedicated to the theme of

'After-Sales Service and Support: The Missing Link in Consumer Protection'

Vahani Scholarship Trust

The Seeds Were Always There

35+

States & union territories reached

77%

Alumni now working in STEM

80%

Scholars are first-generation learners

A Ripple Becomes a Wave

There is a particular Eureka moment Vahani has come to recognise. It is not when the scholarship is awarded. It is years later, when a Vahani Alumni converses with a younger scholar, someone from a similar town and background, sharing a similar set of silences confesses: I have been exactly in the same place.

After a decade of work, that moment is no longer rare. It is being woven into the fabric of the organisation. Alumni are returning as mentors. Mentors are becoming advocates. The community is, in a true sense, beginning to sustain and grow itself.

What began as a scholarship programme has matured into something difficult to express but easier to feel, a living network of people who believe, from personal experiences, that where you begin need not determine how far you go.

The Unfinished Map

India is vast, and Vahani knows it has not yet covered all of it. There are students in remote regions that rarely appear on the radar of scholarship programmes in the northeast, on islands, in communities where a student studies under a regional board's curriculum with no less ambition than her counterpart in a metro city.

The next chapter of Vahani's work and vision is about redrawing that map. Quietly, without a hullabaloo, steadily and surely covering ground, through partnerships with schools, NGOs, and local educators who understand the terrain.

The aspiration is not simply more scholars. It is the right scholars and students for whom this opportunity would otherwise not exist, in fields as varied as medicine, design, law, and the sciences. Students whose admission to a top institution will feel, to their families, like a generation turning on its axis.

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Your generous donation will enable us to sustain our activities and motivate our team to perform in the manner you desire from them to uphold your rights and empower consumers.

Our founder, Prof. Bejon Kumar Misra, a well-known International Consumer Policy Expert, has dedicated 40+years to the consumer movement in India and globally. He has diligently moved forward in empowering the voiceless consumers on their rights and responsibilities, worked on various policy issues, including amending existing laws and regulations, proposing new laws and regulations as per global best practices/standards in the interests of the consumers in India and globally, without any discrimination.

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