



## GOVERNANCE

### What is Clinical Governance?

Broadly defined, clinical governance is maintaining and improving the quality and safety of patient care during a research study. Every clinical site in Australia and New Zealand has its own internal Governance committee responsible for implementing and approving site specific clinical and regulatory guidelines.

### The difference between ethics and governance in clinical research:

Ethics ensure that patient and participant rights, safety and welfare are respected. In the US, Ethics approvals are generally covered by an IRB (Institutional Review Board). Australian Ethics committees are made up of volunteer, specialist and independent reviewers who analyze the protocols, product, device or intervention to assure ethical compliance with human subjects in addition to ensuring the insurances and investigator eligibility to approve the study for conduct under Australian guidelines.

Governance ensures the research study itself adheres to relevant institutional standards, including financial, legal, contractual and legislation requirements – according to the country in which the study takes place. For multi-national

multi-centre trials, this can vary depending on local and regional laws governing clinical studies. The Governance committee is made up of in-house staff at each individual hospital site.



### The 'governing' part of Governance:

Clinical Governance is the set of relationships and functions established by individual hospital sites between its state or territory department of health, governing bodies, executive, workforce, patients, consumers, and other stakeholders to ensure good clinical trial service provision. PCRG enjoys a longstanding and robust relationships with Australian and New Zealand sites and individualize our submissions to reflect the known requirements and very specific nuances from country to country, state to state and from site to site to ensure the most efficient review possible. Our experience means we never 'start from scratch'.

### Why Governance is so important in research

In a word – Assurance. Research Governance establishes standards to improve research quality and safeguard the public. It involves enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring lessons are learned and preventing poor performance and misconduct.

In effect, it assures local authorities, sponsors, sites, physicians and ultimately patients and participants of comprehensive

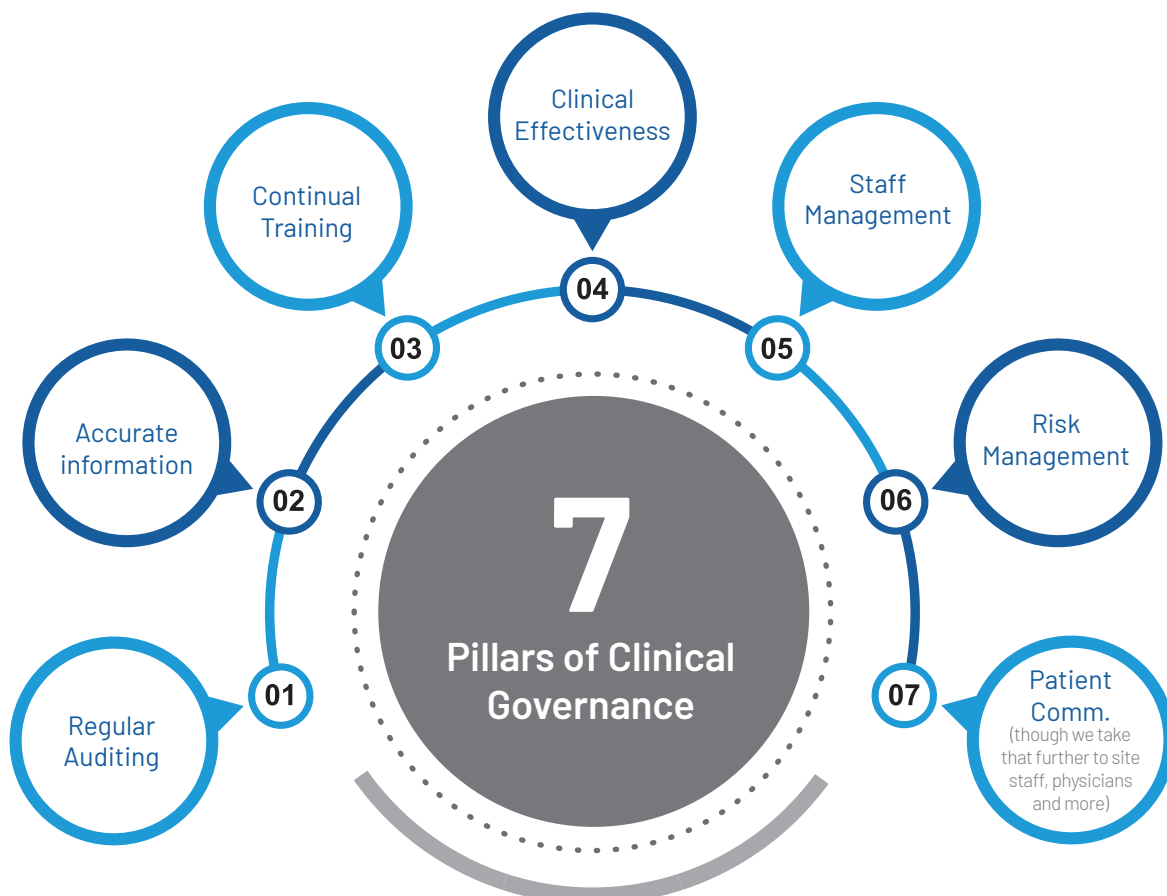
care and continuity throughout the process. Clinical governance is one of the many reasons that study data obtained from Australian and New Zealand is considered Tier 1 data and acceptable for key regulatory pathways, globally.

## Core Principles

Good governance is underpinned by five core principles. An organization that uses good governance is one that always, in word and action, demonstrates:

- Accountability
- Leadership
- Integrity
- Stewardship
- Transparency

At PCRG, we consider the following to be our **Seven Pillars of Clinical Governance**:





## Governance Impact on Data Quality

The ultimate outcome of any clinical study relies on the data collected. Ensuring good quality data is paramount to a successful trial. Rigorous clinical governance ensures:

- Patient data is accurate and up-to-date
- Confidentiality of patient data is respected
- Full and appropriate use of the data is made to measure quality of outcomes (e.g. through audits) and to develop services tailored to local needs.

## What to look for in your CRO's clinical governance operation:

Think "PIRATES":

1. Patient and Public Involvement
2. Information and IT
3. Risk Management
4. Audit
5. Training and Education
6. Evidence-based Practice/Effectiveness
7. Staff Management

After more than 20 years orchestrating and executing trials across Australasia, PCRG deeply understands the nuances of Clinical Governance. This is how we support both our sites and our sponsors.

To learn more about our Governance expertise, please reach out to us [contact@pcrg.com.au](mailto:contact@pcrg.com.au)