UoM Clinical Trial Governance

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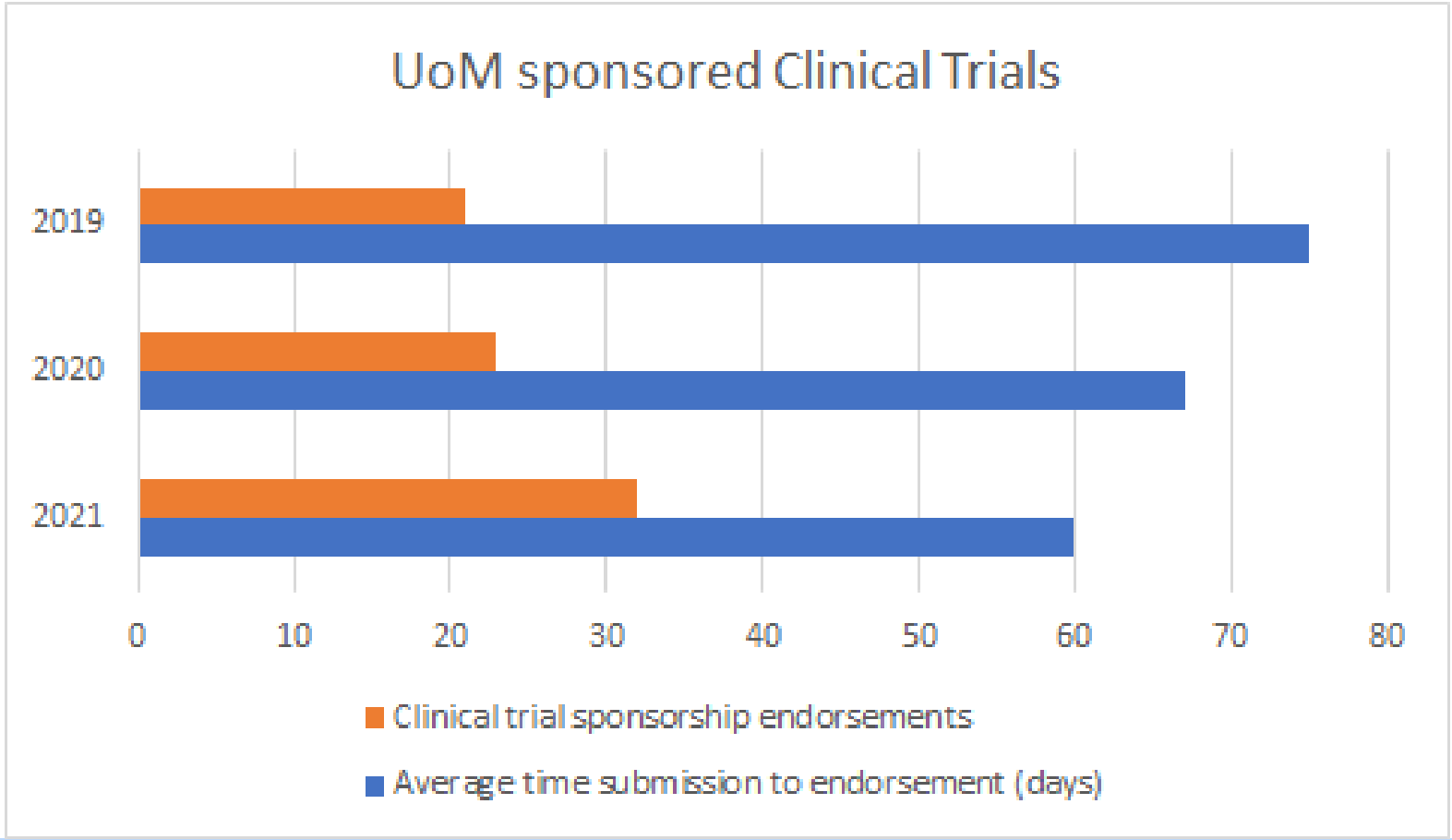
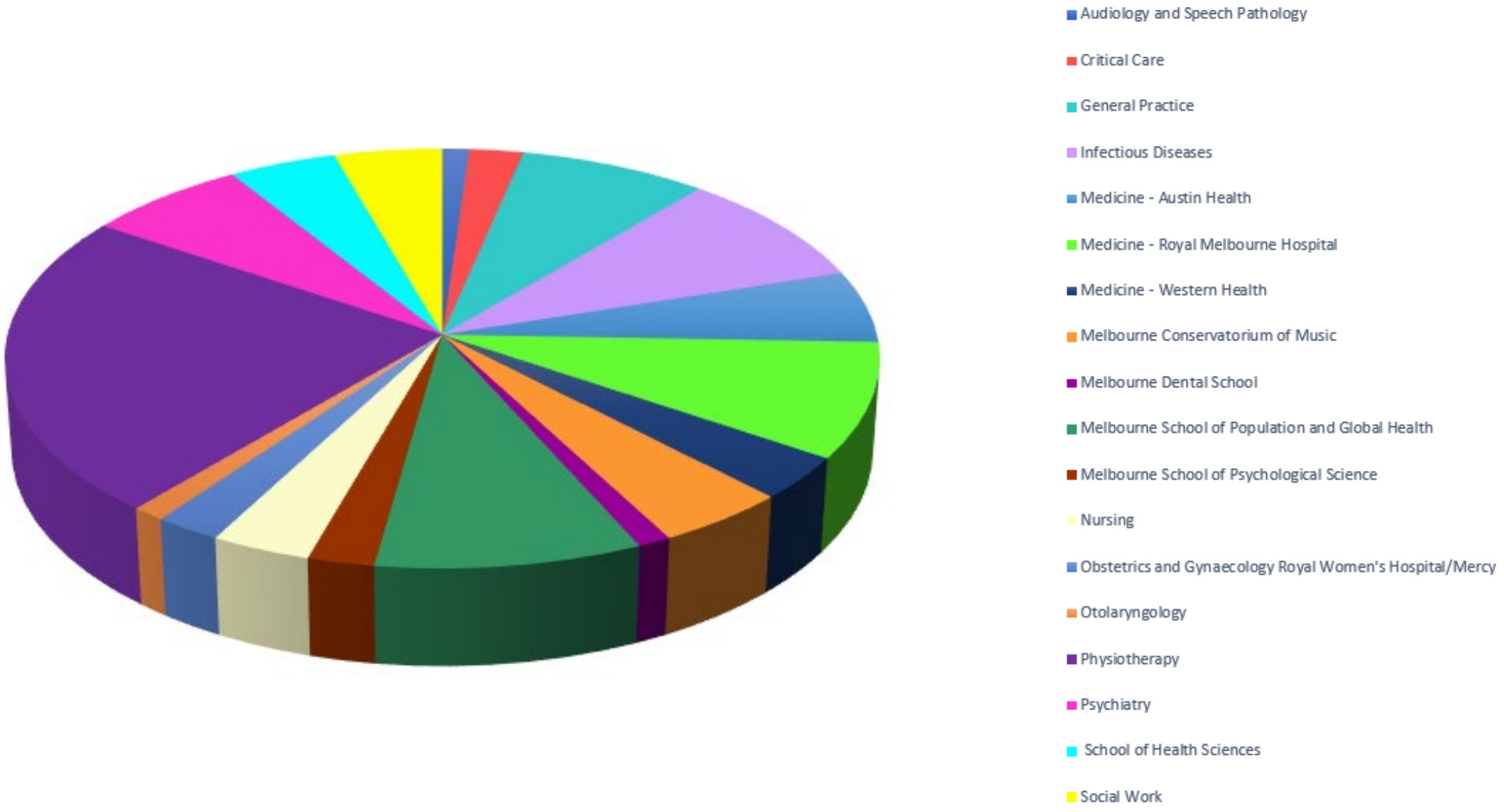
Office for Research, Ethics & Integrity (OREI)

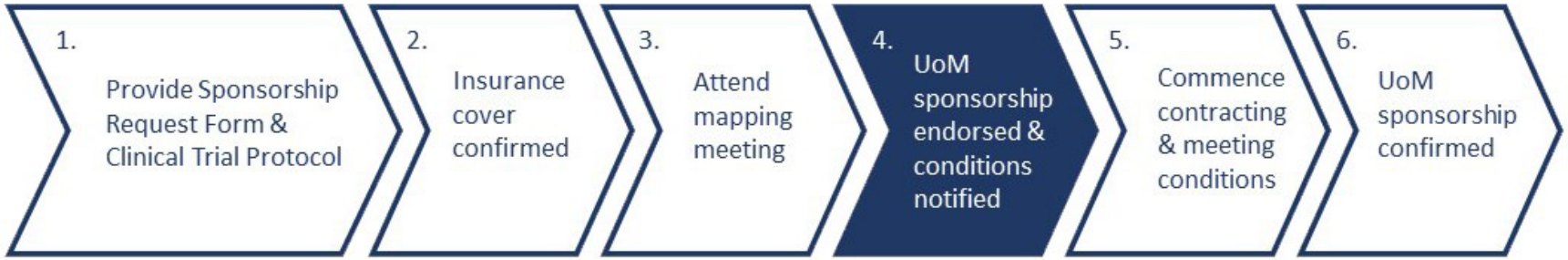
UoM Clinical Trial Sponsorship Activity



UoM Clinical Trial Sponsorship by Department



UoM Clinical Trial Sponsorship Request Process



- Governed by the **Clinical Trial Policy (MPF1352)**
- Process identifies and mitigates institutional risk, where possible.
- Majority of **sponsor responsibilities** are delegated to the UoM Chief Investigator
- Clinical Trial Sponsorship Requests are submitted through the **Infonetica online platform**
- Researchers are concierged through six key stages of the review process
- Representatives from key departments meet with researchers early in the process, ensuring alignment around objectives and needs
- Harmonised communications regarding the status of the application, resulting in greater transparency
- Ethical review remains a separate process, but we recommend submission in parallel to avoid unnecessary delays

UoM Site Specific Assessment Process

- Also governed by the **Clinical Trial Policy (MPF1352)**
- Required when participants are to attend clinical trial visits at the University.
- Can be associated with a sponsorship request or an externally sponsored or collaborative project where UoM is participating as a site.
- Currently submitted via email
- Similar considerations to sponsorship requests:
  - Insurance arrangement
  - Contracting/funding
  - Site and research team suitability
  - Regulatory obligations
  - Ethical

Clinical Trial Governance FAQs

- **Good Clinical Practice (GCP) certification**
  - required for all UoM researhcers directly involved in the conduct of a clinical trial.

- **Clinical Trial Registries:**
  - UoM has a central **ClinicalTrials.gov** account managed by Clinical Trial Governance.
  - Researcher can set up their own individual account for the **ANZCTR.**

- **CTN submissions to the TGA:**
  - Managed centrally through Clinical Trial Governance, this includes **safety reporting**.

- **Ethics:**
  - Public hospitals require review from an NHMRC certified HREC
  - If an external HREC is used the project must be registered with the UoM **Ethics Shared Services (ESS).**

- **Contracting:**
  - Clinical Trial collaborations or UoM initiated research that is not a clinical trial is managed by the Grants/RIC Contracts/Legal and do not need to be reviewed by Clinical Trial Governance.

What's next?

- Continuous improvements to the sponsorship request process under the Business Process Ownership (BPO) model
- Post authorisation governance oversight
- Digitised and streamlined Site Specific Assessment (SSA)
- Update and improve website
- ServiceNow will be developed to support general enquires and project work

For more information or to provide feedback, please visit the Clinical Trials webpage or contact Clinical Trial Governance via phone: (03) 8344 2163 or email: clinicaltrials-governance@unimelb.edu.au

THE UNIVERSITY OF MELBOURNE

Thank you

Office of Research Ethics & Integrity