ChatGPT

Executive Summary

Clinical-trial recruitment in Australia largely relies on **ad hoc clinician referral and patient self-directed searches**, with fragmented information flows. Healthcare providers and patients find trials via government and specialty registries or local apps, then typically require a **physician's referral letter** for formal screening【22†L203-L210】【18†L52-L57】. For example, haematology patients in NSW use the ClinTrialRefer app to identify local trials, but still must get a GP to refer them to a specialist for enrolment 【22†L203-L210】. Patient data are often held in electronic medical records (EMRs) or specialty databases that are not systematically matched to trial criteria. One recent initiative (Torch Recruit) demonstrates that GP EMR data can be algorithmically screened to flag eligible patients【36†L30-L39】, suggesting structured data is available for matching. However, in practice **trial eligibility is mostly assessed manually** by site staff using medical records, and strict criteria exclude many patients【54†L344-L352】.

The **referral journey** typically proceeds from clinician awareness to patient consent via multiple handoffs. A clinician or patient usually first discovers a trial (via search functions on the government registry or other platforms【18†L36-L44】【22†L137-L146】). The clinician then contacts the trial's coordinator (by phone or email) to ask preliminary questions【18†L52-L57】. Patients are then formally introduced (often via a referral letter with clinical history) to the trial site, where research nurses coordinate pre-screening and enrollment. Key transitions occur at: (1) *Patient→GP/specialist* (who must recognize trial eligibility and initiate referral), (2) *GP/specialist→trial coordinator* (transferring referral information), (3) *Trial site staff→patient* (for screening tests and consent), and (4) *Site→Sponsor/CRO* (for reporting). At each handoff, responsibility can be unclear: e.g. patients may end up without a coordinator until a referral letter arrives, and sites lack real-time visibility of referrals coming from external clinics. Communication is primarily via telephone or email, sometimes supplemented by secure online portals for larger sponsors; **paper letters and faxes occasionally persist** in some hospitals (evidence of faxes is anecdotal, not documented in our sources).

Among stakeholders, **Principal Investigators (PIs)** and **study coordinators/research nurses** at trial sites bear major responsibility for eligibility review, data collection, and patient follow-up. PIs must follow the approved protocol and obtain ethics approvals【24†L263-L272】, while coordinators manage ethics/Governance applications and perform much of the screening and recruitment work【28†L269-L277】【28†L305-L313】. **GPs and specialist clinicians** act as gatekeepers to trial enrollment; many lack time or awareness to consistently refer patients【18†L36-L44】【43†L41-L51】. **Sponsors and CROs** finance and oversee trials, requiring sites to meet contractual and regulatory obligations【31†L65-L73】. **Research Governance Offices (RGOs)** ensure site approvals and resources are adequate before studies start【48†L7-L10】【49†L63-L71】, and Human Research Ethics Committees (HRECs) ensure participant safety and consent processes. Patients and families must meet consent and eligibility criteria; advocates may raise awareness of trials.

Documented breakdowns include **low trial awareness**, especially outside academic centers【16†L219-L227】; **restrictive eligibility criteria**, excluding many potential enrollees【54†L344-L352】; **excessive patient burden** (frequent visits or travel)【54†L344-L352】; and **language/cultural barriers** preventing effective communication for some communities【45†L61-L69】. For example, an Australian review noted less than 30% of eligible patients are offered trials【16†L205-L213】. Rural and minority patients face

higher barriers; only ~1/3 of Victorian trial enrollees come from rural areas【54†L365-L370】, and non-English speakers often lack translated materials【45†L61-L69】. Many of these issues have limited direct automation solutions: for instance, **GPs often don't receive timely trial information about their patients** 【43†L89-L97】, and sites may not efficiently share status updates. Despite fragmentation, innovations are emerging: teletrial networks (linking metropolitan and remote sites) and patient-matching tools are piloted to ease access【60†L114-L122】【36†L30-L39】.

Variation across contexts is notable. In rural areas, *teletrials* and primary-care networks enable local participation【60†L114-L122】, whereas metropolitan centers rely on established site infrastructure. Investigator-initiated trials (often registry-based) may recruit broadly via existing databases, while industry-sponsored trials usually use formal site portals and narrower criteria. Paediatric trials require guardian consent and often involve local clinics (e.g. general practitioner-led studies in primary care【36†L30-L39】). State regulations (e.g. use of National Mutual Acceptance for multi-site HREC review) can affect start-up pace. However, many findings are generic: clinician time constraints, data silos, and complex protocols hinder enrollment across nearly all trial types.

Key evidence gaps include systematic data on how frequently referrals fail at each stage, and how different hospital IT systems (EMRs, CTMS, EDC) interoperate (or don't) in trial workflows. Few sources document the daily practice of referrals outside specific case studies.

UX research priorities would probe: how clinicians currently track referrals and screen patients; what information they need at each step; how patients perceive the discovery and consent process; and which automated aids (e.g. trial-match alerts or referral templates) would reduce burdens without undermining care. Initial research might include interviews with GPs, specialists and trial staff, combined with workflow observation and artifact review (e.g. referral letters, database screenshots).

Possible **opportunity areas for Heidi AI** include:

- **Trial discovery assistants** that surface relevant studies for a given patient (addressing awareness gaps)
- **Automated pre-screening** using EHR data to suggest eligibility to clinicians (with final review by humans)
- **Intelligent referral generation** (auto-populating referral letters from patient records)
- **Consent/eligibility explainers** that translate criteria into plain language (for clinicians or patients)
- **Status dashboards** tracking referrals and screening tasks across teams.

Each would require human oversight: e.g. clinicians must verify AI-suggested matches. Privacy, consent, and data security (especially under Australia's privacy laws) are paramount, as is ensuring any AI support is transparent and fair (e.g. not biasing access by geography or language).

Evidence gaps remain around the precise roles of electronic systems (CTMS, EDC) in current practice, and quantitative prevalence of failures (e.g. "how often do referrals lack data?"). Further ethnographic study will clarify these points.

1. Ecosystem and Responsibilities

Actor	Role in journey	Key activities	Decisions	Information needed	Systems/artefacts	De
Patient / Participant	Potential trial enrollee	Searches for trials; discusses options with doctor; provides consent and medical info; attends screening; completes questionnaires.	Whether to pursue trial participation; providing accurate history.	Personal health history, treatment history, current status; trial info.	Patient portal, trial info websites (australianclinicaltrials.gov.au), referrals.	De cli re ref tri inf
Carer / Family	Support decision-making (especially minors)	Supports patient through decision; may communicate with clinicians; helps understand trial info.	Assisting patient consent decision.	Trial information, patient medical info.	Printed info sheets, discussions.	De pa co co lis inv

Actor	Role in journey	Key activities	Decisions	Information needed	Systems/artefacts	De
General Practitioner (GP)	First-line clinician; gatekeeper / referrer	Identifies potential trial opportunities (patient or doctor-initiated); reviews patient data; writes referral letter to specialist or trial.	Decide if patient fits trial context enough to refer; advise patient.	Clinical data from EMR; knowledge of trials (via ANZCTR, apps); referral templates.	EMR; government and specialty trial search (e.g. ANZCTR, ClinTrialRefer app)【22†L137-L146】; referral forms/letters.	De sp te inf inf pa op
Specialist / Treating clinician (e.g. oncologist)	Treating physician; potential site PI or referrer	Reviews patient for trial eligibility; may run trial at their center; communicates trial options to patient; writes or accepts referral.	Whether to initiate referral or enrol patient in trial.	Detailed medical data, trial protocols, inclusion/ exclusion lists.	Hospital EMR; local trial listings; referral or sign-off on referral letters.	Wo res co ne tri
Principal Investigator (PI)	Trial lead at site	Oversees conduct of trial at site; ensures protocol adherence; signs off eligibility; ensures patient safety; supervises team.	Approves patient for enrollment; allocates site resources; compliance decisions.	Full trial protocol, patient clinical data, consent docs.	Investigator Site File (paper/ electronic); CTMS; EDC; patient charts.	De sp pr res go ap co fo

Actor	Role in journey	Key activities	Decisions	Information needed	Systems/artefacts	De
Study Coordinator / Research Nurse	Site coordinator / data collector	Manages day-to-day trial operations: submits ethics/ SSA applications; screens referred patients; collects data; liaises between PI, sponsor, HREC/RGO, and patient.	Determines initial eligibility for screening; allocates study tasks; reports issues.	Patient medical history, lab results; trial eligibility criteria; ethics/SSA docs.	Investigator Site File (ISF); screening logs; lab databases; hospital EMR; eCRF/EDC system.	Re de de lab fo inf sp
Recruitment Officer / Team	(At larger centers)	Actively contacts known patients (from registries or clinics); tracks recruitment targets; liaises with referring clinics.	Prioritize leads; escalate referrals to coordinators.	Patient lists, trial eligibility, referral status logs.	CRM or CTMS; spreadsheets; hospital appointment systems.	Wo stu co an fo pa
Hospital / Health Service	Site management; provides research governance	Facilitates research through governance (RGO); provides clinical resources; may have site feasibility processes.	Approves resourcing (via SSA); allocates space/staff; monitors audit outcomes.	Project proposals, budgets, resource needs, safety data.	RGO application forms; site-specific assessment (SSA) systems; finance systems.	De RG fe sp co

Actor	Role in journey	Key activities	Decisions	Information needed	Systems/artefacts	De
Sponsor (pharma/ CRO)	Trial funder and manager	Designs protocol; provides drug/ device; funds trials; monitors progress; audits sites.	Where to open sites; patient slots allocations; go/no-go recruitment decisions.	Aggregate trial data, site updates, regulatory documents.	Sponsor portals; CTMS; monitoring reports; CRO toolsets.	De sit re re bo ap
CRO (Contract Research Org.)	Sponsor's delegate	Manages trial logistics on sponsor's behalf: site training, monitoring, data collection oversight.	Similar to sponsor: site selection, patient enrollment targets.	Protocol, site data, regulatory updates.	Same as sponsor (often uses sponsor's systems).	Ac sp co wi fo
Regulators / Ethics (HREC)	Ethical oversight	Reviews/ approves trial protocol and materials (consent forms); monitors safety.	Approve or require changes to trial conduct; approve consent docs.	Protocol, consent forms, patient info sheets, adverse event reports.	Ethics submission portals; document archives.	Re sp inf up m

Actor	Role in journey	Key activities	Decisions	Information needed	Systems/artefacts	De
Research Governance Office (RGO)	Institutional approval	Reviews Site-Specific Assessment (SSA): verifies resources, risk management, insurance.	Approves hospital participation; may impose local conditions.	SSA form with project details, budgets, CVs, insurance docs.	SSA submission forms; governance databases.	Co wi de sp

Note: The above roles and activities are drawn from Australian policies and practice examples【24†L263-L272】【28†L269-L277】【31†L65-L73】【18†L52-L57】【60†L114-L122】. These sources describe responsibilities of PIs, coordinators, sponsors and government bodies. They reveal, for instance, that PIs must follow approved protocols【24†L263-L272】, coordinators handle ethics and screening tasks【28†L269-L277】【28†L305-L313】, sponsors secure approvals and financing【31†L65-L73】, and RGOs require a Site-Specific Assessment (SSA) for trials at hospital sites【48†L7-L10】. Because workflows vary by organization, evidence often comes from individual institutions (single-context observations) or general guidelines (direct evidence).

2. Current-State Participant Journey

Overview: In Australia, the typical path from trial awareness to enrolment is:

1. **Trial awareness** (by patient or clinician)
2. **Potential participant identification** (clinician or patient realizes a possible match)
3. **Preliminary matching / pre-screening** (clinician or coordinator reviews basic eligibility)
4. **Referral** (patient is referred to a trial site)
5. **Referral review** (site team verifies the referral and information)
6. **Formal screening (clinical)** (in-depth eligibility tests by site, e.g. labs, scans)
7. **Consent** (patient consents to participation)
8. **Enrolment or non-enrolment** (decision and if enrolling, begins trial interventions)

Intermediate exit paths include: referral declined (not enough info), patient withdraws interest, ineligibility found, or trial closes.

Below is a staged journey with key actors, actions, inputs and handoffs. Alternative flows and failure modes are noted.

Stage	Primary actor	Activities	Inputs	Systems / Channels	Decis outp
Trial Awareness	Patient, GP or specialist	- Search trial listings (ANZCTR, Health.gov) or hear via other sources (media, advocacy groups). - Use specialty apps (e.g. ClinTrialRefer) or websites.	Patient's diagnosis / disease Internet/ registry access	ANZCTR website, australianclinicaltrials.gov.au【18†L36-L44】, specialty apps (e.g. haematology app【22†L137-L146】), info brochures.	Ident one c poter trials
Potential Identification	Clinician or patient	- Clinician reviews patient record or listens to patient history. - Patient notes eligibility hints and may mention trials.	Trial inclusion/ exclusion criteria EMR data	Clinical consultation; EMR (GP or hospital records).	Cand matc flagg (infor

Stage	Primary actor	Activities	Inputs	Systems / Channels	Decis outp
Preliminary Eligibility	Clinician (often specialist)	- Clinician or coordinator compares patient's key data to trial criteria (e.g. age, diagnosis). - May run basic lab tests if needed.	Patient's current health data (labs, history) Trial synopsis	Chart review; phone consult with trial coordinator.	Roug judgr "likel eligib "unlik
Referral Initiation	Referring clinician (GP or specialist), or patient	- Prepares referral package: usually a letter summarizing patient history, diagnosis, and reason for interest. - May include lab results, imaging, pathology reports.	Referral letter draft Patient records, test results	Email or fax or secure upload to research site Phone call to coordinator【18†L52-L57】	Refer with info & intere
Referral Reception	Trial site coordinator / nurse	- Receives referral materials. - Reviews completeness; may contact referrer for missing details. - Logs referral in site tracking system or diary.	Referral letter and attachments from referrer	Email, fax, or secure portal; phone follow-up.	Refer accep "to sc or ret decli info l

Stage	Primary actor	Activities	Inputs	Systems / Channels	Decis outp
Referral Acknowledgment	Trial site coordinator	- Contacts referrer (often GP or specialist) to acknowledge receipt. - Provides patient info on next steps (e.g. paperwork, appointment).	Contact information from referral; appointment schedule	Phone or email to referring doctor and/or patient.	Confi mess refer patie scree appo sche
Pre-screening	Trial screening nurse/ coordinator	- Calls or meets patient to collect baseline info (medical history, concomitant meds). - Orders/schedules preliminary tests per protocol (labs, ECG, imaging).	Referral data; patient interview; EMR as available	Phone, clinic visit; hospital lab systems; EMR notes.	Comp data eligib decis

Stage	Primary actor	Activities	Inputs	Systems / Channels	Decis outp
Formal Screening & Eligibility	Principal Investigator and team	- Reviews test results and full patient data against trial criteria. - Conducts any remaining assessments (e.g. ECG, physician exam, biomarkers).	Full medical record; trial protocol with inclusion/exclusion	EHR; lab/imaging reports; trial screening log.	Deter eligib not a proce conse exclu
Consent	PI or delegated clinician	- Thoroughly reviews study information with patient; obtains informed consent (documented). - For minors/ impacted patients, obtains guardian consent.	Participant Information and Consent Form Discussion of risks/benefits	Consent forms (paper or eConsent); private meeting.	Signe conse allow proce
Enrolment (or non-enrolment)	Trial team (PI/ Coordinator)	- If consented and eligible, patient is formally enrolled and assigned study ID. - If not enrolled, patient may return to standard care.	Completed screening assessments; consent form.	Electronic CRF or enrollment log; hospital records.	Patie statu (enro exclu recor enrol sched interv

Notes on this journey:

- **Alternative entry points:** Patients might self-identify via trial websites and approach either their GP or a specialist directly. Or patient advocacy groups may prompt trial interest. Some sites use registries to invite known patients (e.g. cancer registries).

- **Sequential vs. parallel activities:** Referral processing and initial screening (history-taking) often overlap; e.g. as soon as referral is logged, a coordinator may call the patient before all records arrive to speed the process.

- **Decision points:** Key decisions include (a) deciding to refer, (b) coordinator's assessment of referral viability, (c) final eligibility determination, (d) patient's decision on consent. Each has a potential "no-go" path ending recruitment.

- **Wait points:** Often the patient and referrer wait between sending a referral and hearing back. Patients may also wait for test results, and for trial slot availability.

- **Ownership changes:** Early stages are owned by referring clinician, then handed to site coordinator, then PI/team. Ambiguity can arise e.g. if a patient sees multiple specialists; ensuring one "owner" is important.

- **Failure risks:** Common failure modes are unacknowledged referrals, incomplete information, eligibility failures, patient withdrawal, or trials closing early【54†L344-L352】【45†L61-L69】. Delays here can mean "screen failure" if patients deteriorate or criteria change.

Evidence: The above workflow is synthesized from Australian guidelines and studies. Government guidance describes contact with a trial coordinator and that staff "decide likely eligibility"【18†L52-L57】. Site protocols (e.g. cancer centre referrals) emphasize detailed referral letters【13†L7-L15】. Literature notes that identification and referral are often informal and inconsistent【16†L219-L227】【22†L203-L210】. A published clinical trial experience in remote Queensland illustrated the use of a teletrial model (primary site with remote satellites) but reaffirmed that close collaboration and communication are needed at each handoff【60†L114-L122】【60†L136-L144】.

3. Detailed Handoff Analysis

The table below analyzes key information handoffs between actors:

Handoff	Sender	Recipient	Information transferred	Method	Expected action	Ownership	Failu
Patient → GP / Specialist	Patient or family	GP / Specialist	Patient's symptoms, history, request trial info	In-person consultation	Recognize trial fit; initiate referral if appropriate	GP/ Specialist	Patie men clini
GP → Specialist / Site	GP / Specialist	Trial site coordinator or specialist (next)	Referral letter (patient history, diagnosis, imaging, labs)	Email, fax, electronic referral form	Register patient interest, set up screening	GP → Site Coordinator	Refe inco trans failu

Handoff	Sender	Recipient	Information transferred	Method	Expected action	Ownership	Failu
Site Coordinator ↔ Referrer	Site coordinator	Referring GP/ Specialist	Acknowledgment of referral; questions for clarifications	Phone or email	Provide feedback; request more data if needed	Coordinator	No r itera forth
Site Coordinator → Patient	Site coordinator	Patient	Screening appointment details; consent info sheet	Phone call / mail	Attend screening visit; return forms	Coordinator	No c cont patie
Patient → Screening Team	Patient	Screening nurse/ Coordinator	Medical history; current meds; signed consent (if at enrollment)	Clinic visit; phone	Complete questionnaires; undertake tests	Coordinator	Patie misu parti
Screening Team → PI	Coordinator/ Research nurse	Principal Investigator	Screening data; test results; eligibility assessment	Internal meeting / eCRF	PI reviews and finalizes eligibility	Coordinator → PI	Lost coor misi crite
PI → RGO / HREC	PI / Sponsor	RGO / HREC	Protocol amendments; serious adverse event reports	Formal submissions	Update governance records; maintain approvals	Sponsor / RGO	Late repo non-
Site → Sponsor / CRO	PI / Coordinator	Sponsor/ CRO	Enrollment logs; source data; monitoring reports	CTMS/EDC uploads; emails	Confirm enrolment; data validation; decide next steps	Sponsor / CRO	Data dela entr
Sponsor/ CRO → PI / Site	Sponsor / CRO	PI / Coordinator	Queries on data; updates to protocol; budget info	Email/portal	Respond to queries; implement changes	Sponsor / CRO	Com gaps fail

Key insights from handoffs:

- *Clinical Referral (GP→Specialist/Site)*: In practice, this often is a **free-text medical referral letter** containing all relevant patient records【13†L1-L9】. For example, Cancer site guidelines explicitly ask for recent scan results, lab reports, etc.【13†L7-L15】. This ensures the trial team has the data to pre-screen. Digital referrals (via secure email or EHR messaging) are growing but many still use fax or email attachments (particularly in multi-organizational referrals).

- *Coordinating referrals*: No formal system ensures acknowledgments. Referring doctors often get no automated receipt, so they may not know if a referral was seen. This handoff is largely manual: *the coordinator rings or emails to confirm* or to ask for missing information【18†L52-L57】【22†L203-L210】. If this fails (e.g. referrer doesn't answer), important clarifications may never occur, delaying screening.

- *Between site staff*: The screening process is managed internally. Coordinators and PIs exchange structured data (labs, imaging) mostly via the site's internal systems (paper charts, EMR, or trial CRFs). VCCC guidance shows coordinators collect data into case report forms and inform the PI【28†L305-L313】. Potential failure here is poor data re-entry or miscommunication of protocol criteria (leading to screening errors).

- *Cross-organisation flows*: A critical handoff is **Site→Sponsor/CRO** at enrolment: sites must report enrolment and key data, and **Sponsor→Site** with any queries. Sites often use sponsor-supplied CTMS or EDC; failures like technical glitches or non-integrated data mean sites often duplicate entries. Although we lack Australian specifics, globally it's known that sponsor-site communications (queries, data clarifications) are a frequent bottleneck.

- *Digital vs. manual*: Many handoffs remain **unstructured**. For example, the initial referral is typically a narrative letter, and sites may fax back documents. Few shared digital forms exist. The absence of standard interfaces causes duplicated work: patient data entered in one system (GP's EMR) is cut-pasted into another (CTMS or paper forms).

In summary, each handoff involves **sending medical or trial information** via **email, phone or paper**, with the receiving party expected to take specific actions (screen, reply, schedule). Ownership shifts from the referrer to the trial team, but often without formal acknowledgment. The **risks** are delays, missing data, or loss of patients when communication fails. For example, literature notes many oncology referrals depend on informal networks【16†L219-L227】, implying that if a clinician isn't personally in touch with a trial center, the patient may slip through gaps.

4. Systems and Information Flow

Key systems and artefacts in Australian trial workflows include official registries, hospital records, sponsor databases, and various forms.

- **Clinical Records (EMRs / EHRs):** Patient health data (history, labs, radiology) are originally recorded by GPs and hospitals in their EMRs. These records are the primary source for eligibility info. In Australia, many GPs use systems like MedicalDirector or Best Practice, and hospitals use Cerner, Epic or local EHRs. Most patient data (e.g. blood tests, diagnoses) are **structured**, but trial matching rarely leverages this automatically. (An exception is the Torch Recruit pilot, which uses GP EMR data to identify trial-eligible patients【36†L30-L39】.) Usually, relevant data are manually extracted from EMR by clinicians or trial staff.

- **Government / Public Registries:** The Australian New Zealand Clinical Trials Registry (ANZCTR) is the official registry for all registered trials【18†L36-L44】. Its database provides details (trial ID, contacts, criteria). The federal **Australian Clinical Trials** portal integrates ANZCTR data with local info and has

search for clinicians and patients【18†L36-L44】. Information here is structured (fields for condition, site, contact), but users complain it's cumbersome to parse【22†L154-L163】. There's no direct integration with clinical systems; users must manually search.

- **Specialty Recruitment Tools:** Sites may use bespoke platforms. E.g. the ClinTrialRefer app for haematology in NSW/ACT aggregates trials into a phone app (with filtering by disease/location)【22†L137-L146】. Omico's ONCTN is an emerging network linking molecular data to trial matching【58†L24-L32】 (partnering population sequencing with trial access). These platforms hold structured trial metadata and possibly some patient info (e.g. search queries or profiles), but they do not exchange data directly with EHRs.

- **Referrals and Screening Logs:** Referral information is often conveyed via **referral letters**, which are essentially unstructured PDFs sent by email or fax【13†L7-L15】. Once received, trial sites log referrals in **spreadsheets or CTMS databases**. Many sites keep a **Screening Log** (often Excel or part of CTMS) to track each candidate's status. These logs hold structured fields (patient demographics, eligibility checkpoints), but they require manual entry of data from letters and tests.

- **Consent Documents:** Participant Information Sheets and Consent Forms are paper or electronic documents (often PDFs or eConsent modules). These contain key trial and patient information. Once filled, copies reside in the trial master file (paper/electronic). They are *not* machine-readable.

- **Hospital Systems:** During screening, sites use their hospital's **EMR/health record** to order tests and record results. They also use the hospital's **appointment scheduling** to set screening visits. These systems are generally not integrated with the trial's CTMS; staff often print or re-enter lab results into the trial's database.

- **Sponsor / CRO Systems:** Larger trials use **Electronic Data Capture (EDC)** systems for case report forms (e.g. REDCap, Medidata, TrialMaster). Sites enter patient data directly into EDC. They may also use a **CTMS** for enrollment tracking. Communication with sponsor or CRO often goes through email or secure sponsor portals. These systems contain structured trial data but are typically siloed (no connection to hospital EHR). Sponsor/CRO also maintain master protocols and trial management docs (unstructured or semi-structured).

- **Communication channels:** Email and telephone remain ubiquitous. Some trial teams use secure messaging tools (e.g. encrypted email, hospital intranet, or messaging apps like Microsoft Teams) for quick queries. Fax is still used at some sites (especially if referring doctors use older systems).

- **Other artefacts:** Paper work (e.g. lab slips, questionnaires), spreadsheets, calendars (for scheduling visits), and even WhatsApp are informally used in some sites for reminders. We found no formal evidence of any single system across sites; use seems site-specific.

Integration / Visibility Issues:

There is **little interoperability** between systems. For example, a patient's blood result in a hospital EHR must be manually re-keyed into the trial's database. This duplication risks errors. Likewise, if a trial spans multiple sites, an enrollment at one site is not automatically visible to another without communication.

No sources provided national system-level evaluations, but cited processes and interviews indicate that information flow is fragmented:

- **Structured data vs. unstructured data:** Patient vitals/labs are structured in hospital systems, but eligibility criteria are usually textual and must be interpreted manually. None of the Australian sources mention widespread use of natural language processing or AI to bridge this gap, except the Torch Recruit project【36†L30-L39】.
- **Visibility:** Neither referrers nor patients typically have a dashboard of referral status. Some sites send progress emails, but often both parties rely on ad hoc calls.
- **Reuse:** Patient data are often copied between documents. E.g., the referral letter information might later be re-entered into screening forms. The VCCC Study Coordinator role description notes maintaining an **Investigator Site File (ISF)** and data entry【28†L323-L331】, implying paperwork duplication.

Evidence of problems:

While no source explicitly audits system handoffs, multiple reports highlight **data gaps and delays** as issues. For example, Nature's review of pancreatic cancer noted delays transferring records during referral to external centers【16†L182-L190】, illustrating inefficiencies when sites and systems are disconnected. Australian accounts of trial participation also note that trial teams often lack "complete or current" patient information if data transfer falters.

5. Breakdown and Unmet-Need Analysis

The following table summarizes identified problems (supported by evidence or clearly inferred from sources), their context, and impact. Each is prioritized by evidence strength and likely scope.

Breakdown / unmet need	Affected actors	Workflow stage	Supporting evidence	Evidence of prevalence	Consequence	Exist work
Limited trial awareness: Many patients and GPs do not know of all relevant trials (especially outside major centers).	Patients, GPs, specialists	Trial awareness → identification	• Only ~27% of cancer patients report being offered a trial【16†L205-L213】; under-80s more likely • ClinTrialRefer case: even with apps, coverage was regional【22†L154-L163】.	Multiple reports (oncology survey【16†L205-L213】); app uptake in NSW suggests local solution.	Patients miss opportunities; recruitment slower, biased to informed centres.	Use c regist (ANZ ACTr) effort

Breakdown / unmet need	Affected actors	Workflow stage	Supporting evidence	Evidence of prevalence	Consequence	Exist work
GP time/ knowledge constraints: GPs often lack time or sufficient trial knowledge to discuss trials or refer.	GPs, patients	Identification, referral	• Editorial: GPs' busy schedules, lack of trial familiarity limit referrals【43†L42-L51】. • Dashboards/tool use low in primary care.	Qualitative reports in Australia (breast cancer example 【43†L42-L51】).	Eligible patients not sent to trials; patients trust GPs for info.	Some resea netwo enga (Torch or liai staff.
Complex eligibility criteria: Many trials have stringent or complex criteria that are checked manually, leading to high screen-failure.	Trial coordinators, patients	Formal screening	• VCCC: "complex trials can have narrow eligibility... making it harder for patients"【54†L349-L352】. • Literature: ~50% of patients meet strict criteria【16†L244-L252】.	Cancer reviews; VCCC commentary; international surveys suggest similar challenges.	High screening failure; delayed enrolment; patient drop-out due to onerous testing.	Manu scree check coord
Incomplete referrals: Referral letters or forms often miss key data (old results, contact info), requiring back-and-forth.	Coordinators, referrers	Referral initiation/ review	• Scientia example: advises including "most recent tests and reports"【13†L7-L15】, implying common shortfalls. • Anecdotal: missing pathology often delays screening.	No systematic audit, but clinical practice widely acknowledges incomplete referrals.	Processing delays; potential candidate loss; extra workload for clarifications.	Coord conta refer missi may resch
Referral delays / no acknowledgement: Referring clinicians/ patients may wait without confirmation that referral was received or is being acted on.	Referrers, patients, coordinators	Referral review	• No official source; inferred from the lack of structured systems and need for coordinators to call back【18†L52-L57】.	Common experience mentioned in forums; lack of documented process suggests prevalence.	Patient uncertainty; duplicated referrals; attrition of referrals.	Docto follow phon temp stress

Breakdown / unmet need	Affected actors	Workflow stage	Supporting evidence	Evidence of prevalence	Consequence	Exist work
Poor visibility of status: Once referred, referrer/ patient often cannot track progress; site sponsors may not update easily.	Patients, referrers	Throughout	• Observational inference: discussion notes lack of automated updates. Rare usage of portals by patients.	Evidence gap (no reports found); inferred as problem by context.	Anxiety and confusion; possibly redundant follow-ups.	Manu phon upda coord ad ho
Geographic / access barriers: Patients in rural/ remote areas face travel burdens to reach urban trial sites (often multiple visits).	Patients (rural), families	Screening/ enrollment	• Queensland case: 90% of trials urban; travel burdens significant 【60†L101-L109】. • VCCC: rural patients <33% of enrollees; travel distance a common drop-out reason 【54†L344-L352】 【54†L365-L370】.	Strong: state reports, trial network data. Teletrial uptake increasing in response.	Rural patients under-represented; inequity in access; trial targets unmet in those regions.	Teletr regio hubs; cover trave partia
Cultural/language barriers: Non-English-speaking or low-literacy patients struggle with trial info and consent.	Patients (CALD, Indigenous), clinicians	Consent/ communication	• Study: Arabic-speaking patients face language barriers; lack of translations hurt enrolment 【45†L61-L69】. • Note: Indigenous patients historically underrepresented.	Direct study on Arabic-speakers; Australian cancer stats show disparities 【16†L229-L237】.	Lower enrollment of minorities; possible consent issues.	Use c interp trans forms cultu adapt conse proce
Data re-entry and siloed systems: Patient info must be manually transferred between EMR, spreadsheets, and trial systems, risking errors.	Coordinators, trial monitors	Referral to enrolment	• Inferred from lack of integration across systems 【28†L305-L313】; common industry knowledge.	No specific AUS data, but multiple governance documents imply record duplication.	Inefficiency; transcription errors; staff burden.	Doub entry CTMS using stand forms

Breakdown / unmet need	Affected actors	Workflow stage	Supporting evidence	Evidence of prevalence	Consequence	Exist work
Trial closing before enrolment complete: Slow referrals can mean trials hit recruitment targets or end-of-recruitment and close.	Patients, sponsors, coordinators	Screening/ enrollment	• In communication (red tape), not explicitly found in sources. Known issue in trials sector (30% trials fail recruitment).	General stat: 30% of trials fail recruitment (cited in media interview 【22†L228-L237】).	Patients lose access; data loss for sponsors; resource waste.	Rarel addre syste some accel scree

Ranking rationale: Problems with strong evidence and broad impact (e.g. awareness, eligibility complexity, rural access) get higher priority. For instance, *limited awareness* is supported by patient surveys【16†L205-L213】 and directly leads to lost participants; it's a priority for intervention. *Cultural barriers* and *GP constraints* also have strong supporting studies in Australia【45†L61-L69】【43†L42-L51】 and affect equity. Issues like *lack of referral tracking* are plausible but lack data; they are listed with lower confidence as evidence gaps.

6. Workflow Variation

Evidence suggests that core aspects of the trial journey apply broadly, but specific contexts modulate practices:

- **Patient-initiated vs clinician-initiated:** Generally, clinicians initiate referrals. However, some patients actively research trials (especially well-informed or through patient networks) and then prompt their GP. The NHS-style model (direct patient self-referral) is rare in Australia; patients are *advised* to take information to their doctors【18†L36-L44】. No evidence of direct patient enrolment without physician involvement.

- **Investigator-initiated vs Industry-sponsored trials:** Investigator-initiated trials (often academic or registry-based) may have simpler criteria and fewer bureaucratic controls【54†L355-L363】. They may recruit via research registries and directly through clinics. Industry trials usually run through contract processes and use standardized protocols; referrals go through sales or research teams. However, the referral and eligibility steps (GP finds trial → coordinator screens → consent) are largely similar. Sponsor type mostly affects who operates the trial (academic PI vs pharma) and associated SOPs, but not the participant-facing journey.

- **Public vs private sites:** Most recruitment happens in public hospitals and associated research institutes (cancer centers, major hospitals). Private clinics occasionally run trials (e.g. private oncology practices). Private sites likely have fewer bureaucratic layers (some ethics/governance differences), but still use similar referral channels. No Australian source contrasts public vs private explicitly. We infer that public hospitals (with Research Governance Offices) may add extra steps (SSA), whereas private clinics (if participating) might rely on external ethics committees and have simpler sign-off.

- **Single-site vs multi-site trials:** Single-site trials at a major center only require local referral patterns. Multi-site trials (common for industry-sponsored drug trials) entail **Site-Specific Assessments (SSA)** at each hospital【48†L7-L10】 and possibly a lead-site ethics. This means referral could go to multiple locations. In practice, if a patient is ineligible at one site or trial, the team might suggest another site if available, but this is ad hoc. Australian Teletrial suggests multi-site coordination (primary vs satellite) but actual referral transfer between sites (e.g. patient switches site) is uncommon and not documented.

- **Geographical setting (metro vs rural):** In metro areas (e.g. Sydney, Melbourne), there are multiple trial centers, so a patient can often go to one near home. Referral may be to the "home hospital". In rural/regional areas, specialized trials may not exist locally. Here, teletrials come into play: a local hospital (under Australian Teletrial Program) can run the trial under the auspices of a metro PI 【60†L114-L122】. The patient may never leave town (except for some initial visit), with local nurses doing assessments. This changes the journey: referrals stay local, telemedicine bridges the rest. Evidence: Queensland's QRCCC uses teletrial methodology so rural patients engage with trials without travel【60†L114-L122】.

- **Early-phase vs late-phase trials:** Early-phase (Phase 1) trials often have stricter monitoring (frequent visits, lab work) and are only at specialized centers. Patients may need more intensive screening (molecular profiling). Industry's logistic differences (e.g. needing hospitalization for first dose) alter the "commitment burden"【54†L344-L352】. Later-phase trials (Phase 3) might have broader eligibility and more sites, so referrals might flow to whichever site is recruiting locally.

- **Intervention type (drug, device, behavioral):** Most evidence here is from drug trials (oncology). Device or diagnostic trials might have different pre-screening (specific imaging or lab tests). Behavioral interventions (e.g. telehealth, smoking cessation) might recruit directly through primary care or communities; referral could be simply handing patient a flyer or contacting a research nurse.

- **Therapeutic area:** Oncology has most documentation. Other areas (cardiology, respiratory, etc.) likely follow similar patterns but may involve different specialists (e.g. cardiologist vs oncologist). Patient organizations in certain fields (e.g. diabetes, mental health) might run their own trial registries or newsletters, which is an alternate discovery channel not broadly captured here.

- **Adult vs paediatric trials:** Pediatric trials require parental involvement. Children's hospitals may coordinate referrals through pediatricians or family doctors. The core steps (GP → specialist → trial) remain, but consent involves guardians. No sources explicitly detail the referral flow for children, but [6] shows Australian guidance that parent/guardian consent (and child assent if possible) is legally required for minors.

- **Jurisdictional differences:** Australia uses the National Mutual Acceptance (NMA) scheme for multi-site ethics (across states)【47†L249-L257】, so some trials have a unified HREC for multiple states. States may have different RGO requirements (as seen with NT Health's RGO procedures【49†L63-L71】). In practice, a trial referral in one state is handled by local site processes, but the overarching legal/regulatory framework is national.

- **Recruiting from existing patients vs broader community:** Some trials (e.g. registry trials) recruit from known patient registries or EHR cohorts; others recruit via media ads and clinics. Registry-based trials simplify screening because inclusion is based on known characteristics, whereas open recruitment faces low awareness. The VCCC article notes "registry trials ask straightforward questions, allowing wider selection criteria"【54†L355-L363】, implying that if patients are identified via registry (existing care), eligibility is often pre-validated (less formal screening burden).

Applicability of findings: Many of the issues identified (low awareness, manual eligibility checks, referral delays) appear across contexts, particularly in cancer trials. However, context matters: for instance, teletrial solutions are specific to rural settings, and the ClinTrialRefer app example is specific to haematology in NSW. Similarly, GP engagement (Torch Recruit) is specific to primary care research in some chronic disease areas. The core theme—that trial recruitment is fragmented and relies on human coordination—is broad. But specific channels (specialty apps, regional networks) vary by area and condition, which must be considered when designing solutions.

6. Existing Solutions and Remaining Gaps

Trial discovery and matching:

- *Government registry and portal (AustralianClinicalTrials.gov.au/ANZCTR)* – Users: patients, GPs, specialists. Supports trial listing and search. Solves "central information" but is generic; lacks smart filtering and alerting. Limitations: requires manual search; contact info is provided【18†L36-L44】 but navigation is time-consuming【22†L154-L163】. Evidence: Publicly available with guidelines for referrals【18†L36-L44】.

- *ClinTrialRefer app (NSW Haematology group)* – Users: haematologists, patients. Focuses on blood cancer trials in NSW/ACT. Solves quick filtering by disease and location【22†L137-L146】. Limitation: regional (NSW/ACT only) and specialty-specific; not integrated into GP systems. Evidence: ABC interview describing app features and uptake【22†L137-L146】【22†L203-L210】. (Vendor-affiliated but independently reported.)

- *Torch Recruit (University of Melbourne)* – Users: GPs in PARTNER network, researchers. Automates patient eligibility screening from GP EMRs using algorithms【36†L30-L39】. Supports matching primary-care patients (especially regional) to trials. Limitations: still in pilot stage, currently focused on liver disease trial; requires GP network participation. Evidence: University case study describing pilot and rationale【36†L30-L39】【36†L43-L47】.

- *Oncology Mobile Apps / Portals (Victoria NSC, Queensland, etc.)* – Several cancer networks have developed apps (e.g. Victorian Oncology Trials App). These list local trials. Solves: clinician awareness at point-of-care. Limits: similar to ClinTrialRefer, limited to user group. No formal citation, but analogy to ClinTrialRefer.

Eligibility assessment and referral management:

- *Australian Clinical Trials (health.gov.au) referral guidance* – Govt resource for clinicians. Users: GPs/specialists. Provides instructions on referring patients, including coordinator role【18†L52-L57】. Solves awareness of process steps, not technology. Evidence: Government website page【18†L52-L57】.

- *Site referral forms/templates* – Many hospitals have their own referral forms (e.g. a form to fill with patient data for trial referrals). Users: GP/specialist referring to that site. Solves: standardizing required info. Limitations: not standardized across sites; still relies on manual fax/email. No authoritative reference found, but widely practiced (Scientia's "referral letter checklist"【13†L7-L15】 exemplifies best practice at one center).

- *Teletrial platforms (ATP/QRCCC)* – Users: site coordinators at remote/rural hospitals. Provide governance frameworks and support for running trials via telehealth【60†L114-L122】. Solve access barriers by formally connecting sites. Limitation: currently mostly in Queensland and expanding to other states; still requires local staffing. Evidence: Government reports describe models and success【60†L114-L122】.

Recruitment and communication tools:

- *Electronic Data Capture (EDC) systems* – Industry solutions (e.g. REDCap, Medidata). Users: site coordinators and PI. Manage patient data, screening logs. Solve: structured data collection and query management. Limits: integration only within trial; no patient matching. (No Australia-specific citation, but these are ubiquitous in clinical research.)

- *Sponsor portals (CRO systems)* – Users: site staff. Provide trial documents, data entry, queries. Solve trial management. Limits: multiple, non-interoperable portals for different sponsors; not patient-facing. (General knowledge; no direct Aussie source.)

- *Email & telephone* – The default communication channel in trials. Users: all actors. Solve ad hoc coordination. Limits: not trackable, prone to omission. (Not documented, but inferred from all sources as primary method.)

- *Project-specific tools (e.g. hospital intranets, shared drives)* – Local teams often use SharePoint or local databases to track referrals. Solve local coordination. Limits: not standardized; no external access. (No published evidence.)

Cross-organization collaboration:

- *Australian Teletrial Program (ATP)* – A national initiative linking state programs. Users: clinicians at rural sites and metro sites. Supports governance sharing (mutual acceptance of ethics), training, and referral of patients via telemedicine【60†L114-L122】【54†L355-L363】. Solves: systematic framework for remote trials. Limitations: still evolving, currently emphasizes oncology trials but expanding. Evidence: Queensland case study【60†L114-L122】, VCCC account of teletrials【54†L365-L370】.

- *Collaborative Groups (e.g. Clinical Trial Networks)* – E.g. National Medicines Policy Committee, Paediatric groups. Users: researchers. They coordinate multi-center trials (rarely affecting referral path for individual patients). No direct citation relevant to referral workflow.

Remaining gaps / limitations:

- **Interoperability:** No mention of any system linking EHRs to trial databases. For example, there is no national "trial alert" system in Australian GP software. This is a major gap; research like Torch Recruit is trying to fill it, but no widespread solution exists yet.

- **Standard workflows:** No single standard for referrals or tracking is mandated. Processes vary by site. This fragmentation means solutions tend to be local/specialty rather than universal.

- **Patient engagement tools:** Apart from websites, there are no widely-used patient self-referral or matching platforms in general healthcare in Australia (unlike some initiatives in the US).

- **Monitoring / Notification:** No evidence of tools that track and notify referring physicians of patient progress. Many referrers rely on periodic queries.

In summary, existing Australian solutions address parts of the journey (discovery, access, data capture) but often in isolation. The **critical gap** is an integrated support system connecting patient data, trial information, and communication. For example, while ClinTrialRefer helps discovery, it doesn't assist with referrals or eligibility checking once a trial is found. Torch Recruit automates matching but doesn't handle consent. Teletrial programs enable remote participation but don't automate referral coordination. Each tool fixes one "slice" but many needs (like referral management and multi-party visibility) remain unmet.

7. Opportunity Areas for Heidi AI

Based on the workflow and gaps, we identify potential AI-assisted opportunities. Each must respect the boundaries of clinical judgment and privacy.

Opportunity area	User problem	Affected actors	Workflow stage	Evidence	Possible role for Heidi AI	Human oversight
Automated trial matching	Difficulty finding relevant trials quickly.	Clinicians (GPs, specialists); patients	Trial awareness, identification	Clinician reports: ANZCTR hard to use; clinicians rely on memory or local apps【22†L154-L163】【18†L36-L44】.	NLP/ML system that takes patient profile (condition, labs) and returns ranked trial list with key criteria, contacts.	Clinician reviews AI-suggested trials for relevance; patient consents to any outreach.
Eligibility criteria explainer	Complex trial criteria hard to interpret by clinicians and patients.	Coordinators, clinicians, patients	Preliminary matching	Evidence: Trials have many narrow criteria【54†L349-L352】; coordinators manually parse protocols.	Tool that interprets inclusion/exclusion in plain language or translates them into checklists based on patient data.	Human check clarity; final inclusion determined b trial PI.
Referral drafting assistant	Time-consuming to compile patient data into referral format; risk missing info.	GPs, specialists	Referral initiation	Scientia example emphasizes detailed referral letters【13†L7-L15】; GPs constrained by time【43†L42-L51】.	AI that extracts relevant patient data (history, lab values) from EMR and populates a referral letter/template for a specific trial.	Clinician reviews and edits the drafted referr before sending.

Opportunity area	User problem	Affected actors	Workflow stage	Evidence	Possible role for Heidi AI	Human oversight
Patient summary generator	Trial teams need concise patient summaries (avoid repetitive data entry).	Study coordinators, investigators	Pre-screening, screening	Sites collect same patient data repeatedly; no source. Inferred from workflow.	Summarizes patient's relevant history and test results into structured format for trial forms, reducing manual transcription.	Coordinator validates summary accuracy.
Consent support (patient-facing)	Patients often confused by trial info and consent forms.	Patients, clinicians	Consent	Patients vary in info absorption 【43†L63-L71】; non-English speakers struggle 【45†L61-L69】.	Interactive chat interface or digital assistant explaining study purpose, procedures, and answering FAQs in lay terms (multilingual).	Clinician must verify understandin final consent by human.
Referral status tracker	Lack of visibility: patients and referrers don't know where their referral is up to.	Patients, referrers, coordinators	Throughout referral process	No formal system mentioned; in-house communications only.	Notification system that updates authorized stakeholders (referrer, patient) at key milestones (referral received, screening scheduled).	Humans update syster with statuses (or system inferred from actions).

Opportunity area	User problem	Affected actors	Workflow stage	Evidence	Possible role for Heidi AI	Human oversight
Recruitment prioritization	Sites may not identify “hard-to-reach” patients or underrepresented groups.	Research staff, sponsors	Recruitment strategy	Evidence: Under-enrollment of older, Indigenous, rural patients 【54†L365-L370】 【16†L229-L237】.	Analytics tool to identify demographic gaps in current recruitment and suggest targeted outreach (e.g., "no patients age > 70 screened").	Trial manager decide on remedial actions.

Discussion of opportunities:

- *Automated trial matching:* This directly addresses the evidence of low awareness and difficulty searching【22†L154-L163】【18†L36-L44】. An AI could analyze a patient’s coded data (diagnoses, labs, genetics) and match against trial criteria. It would act like a smart filter for ANZCTR. **Risks:** Misidentification (false positives/negatives) could waste time or give false hope. Data sharing: would need patient consent and secure integration with EMR. But because final eligibility check remains with clinicians/trial staff, risk is mitigated. Likely high impact if done safely; similar tools exist in R&D (e.g. AI-trial-matchers used by sponsors internationally, but not AU-specific yet).

- *Eligibility explainer:* Coordinators spend much time parsing complex protocols. AI could translate criteria into checklists or patient-friendly terms. For example, converting “LDH ≤ 1.5×ULN” into “disease marker below threshold.” Humans must always verify. This helps internal efficiency and possibly patient comprehension. It doesn’t automate any final decision.

- *Referral drafting assistant:* GPs have limited time and trial coordinators request detailed referrals 【13†L7-L15】. If an AI could pull the latest labs/imaging from the GP’s record and format a referral letter, that saves clinician effort. However, this requires deep integration with health records (likely via standardized APIs – would need to conform to Australian health IT standards), and strict safeguards. The AI might be uncertain of what to include, so human editing is crucial.

- *Patient summary generator:* Trial teams often manually compile patient histories. An AI could pre-fill eCRF fields or screening logs from clinical data. This reduces redundant entry. Again, integration issues (access to EMR), and oversight needed (staff must proofread). Moderate benefit but could address “repeated data entry” breakdown (currently unquantified).

- *Consent support:* Given evidence of poor understanding and language barriers【45†L61-L69】, an AI “consent coach” (e.g. chatbot explaining in plain language or other languages) could improve patient comprehension. Australian ethics still require human-mediated consent, but an AI tool could

supplement by answering questions. Risk of hallucination or bias means heavy oversight – it would be more of an adjunct to human discussions.

- *Referral status tracker:* The problem of "no one knows where the patient is" could be partially solved by a simple tracking app: after each stage (referral sent, received, screening scheduled, etc.) the site staff log status, and authorized stakeholders get updates. This is more a workflow tool than sophisticated AI. Privacy is less of an issue if properly permissioned. It could reduce redundant follow-ups.

- *Recruitment prioritization:* An AI could analyze the demographics of enrollees in real time and flag under-represented groups (e.g. "no Indigenous patients yet"; "fewer elderly than expected"). This analytics function could inform site strategies (targeted outreach through community clinics, etc.). Ethical oversight needed to avoid bias (e.g. don't target individuals by category, use aggregate guidance).

Each opportunity must carefully guard patient data (Australian Privacy Act) and clinical safety. Heidi AI's suggestions should always require a clinician or human researcher to validate and act. Automation bias is a concern: teams might over-trust an AI suggestion, so UI must emphasize this as decision support, not decision making.

8. UX Research Hypotheses

Based on the above analysis, we propose hypotheses to test. Each includes motivation, assumptions, methods, and potential impact.

1. **Hypothesis: GPs have low confidence in discussing trial options due to limited knowledge and time, leading to under-referral.**

2. *Motivation:* Editorial evidence that GPs often lack trial expertise【43†L42-L51】, and tech (Torch) is being developed.

3. *Assumptions:* GPs encounter trial-eligible patients but don't act due to barriers.
4. *Participants:* Primary care GPs (both research-interested and not), and practice nurses. Possibly clinical trials GPs from the PARTNER network.
5. *Method:* Semi-structured interviews and surveys to gauge awareness, attitudes, and typical referral practices; workflow observation of GP consultations (with patient permission) to see if/how trial discussions occur.
6. *Key questions:* How do GPs decide whether to discuss trials? What information/tools do they currently use? What stops them from referring?
7. *Supporting evidence:* If GPs report "I didn't know about any trial for this patient" or "I didn't have time to check", that supports the hypothesis.
8. *Contradictory evidence:* If most GPs are already aware and regularly refer or use some system, hypothesis false.

9. *Product impact:* If confirmed, Heidi could focus on making trial info accessible to GPs (e.g. integrated search, alerts) and addressing time constraints (e.g. quick-match tools).

10. **Hypothesis: Trial eligibility checklists and criteria are difficult to use during busy clinics, causing delays or inaccurate referrals.**

11. *Motivation:* Complexity of criteria is a known burden【54†L349-L352】.

12. *Assumptions:* Clinicians cannot internalize lengthy criteria, so referrals may omit borderline patients or waste time on clear non-eligibles.
13. *Participants:* Specialist clinicians (oncologists or others running trials), research nurses/coordinators.
14. *Method:* Cognitive walkthroughs and contextual inquiry: ask participants to simulate checking eligibility for a hypothetical patient using real trial protocol excerpts. Also, interview about pain points (e.g. criteria overload).
15. *Key questions:* How do you currently apply inclusion/exclusion criteria? What tools (if any) do you use?
16. *Supporting evidence:* Clinicians express difficulty or make mistakes when using protocol text; coordinators must often exclude patients after detailed review.
17. *Contradictory evidence:* If they use internal checklists effectively and have no trouble.

18. *Product impact:* Confirmation suggests a need for decision support (e.g. streamlined checklists or AI explainers).

19. **Hypothesis: Patients feel uncertain and anxious due to poor communication about referral status and next steps.**

20. *Motivation:* No evidence found, but logically, lack of updates can worry patients.

21. *Assumptions:* Patients expect to be informed after referral and may be left waiting.
22. *Participants:* Patients who have been referred for trials (both enrolled and not enrolled). Family members could be included.
23. *Method:* Patient interviews or surveys after referral to assess their experience. “What did you know and when?” Also diary studies (ask patient to note interactions).
24. *Key questions:* Did someone contact you after your doctor mentioned a trial? What were you told would happen? How long did you wait?
25. *Supporting evidence:* Patients report confusion or no news for weeks.
26. *Contradictory evidence:* If sites routinely update patients, this may be rare.

27. *Product impact:* Validates need for notification system or patient-facing dashboard.

28. **Hypothesis: Site coordinators spend significant time entering patient data into multiple systems, detracting from patient interaction.**

29. *Motivation:* Workflow suggests duplication (EMR → eCRF → database).

30. *Assumptions:* Coordinators manually re-enter data and find it inefficient.
31. *Participants:* Study coordinators, research nurses.
32. *Method:* Time-tracking observation: measure how much time is spent on data entry vs other tasks. Interview on tools used.
33. *Key questions:* Which systems do you enter data into? Which tasks are most time-consuming?
34. *Supporting evidence:* Coordinators describe copying info from hospital record to trial form.

35. *Contradictory evidence:* If coordinators primarily use integrated systems or if most data is already digital.

36. *Product impact:* High support for AI summarization or integration tools to reduce duplication.

37. **Hypothesis: Clinical trial information sources are not integrated into clinician workflows (EMRs or EHR decision support), leading to missed matches.**

38. *Motivation:* Current tools (websites, apps) are external; none inside clinic software.

39. *Assumptions:* GPs/specialists do not search trials during patient visits because it's inconvenient.
40. *Participants:* Clinicians who have ever had an eligible patient.
41. *Method:* Ask clinicians to describe how/when they look up trial info. Possibly a survey question on whether they use patient-oriented vs doctor-oriented sites. Examine if any clinical software integration exists.
42. *Key questions:* "If a trial were available for your patient, how would you know?" "Have you ever used a clinical prompt or EMR feature for trials?"
43. *Supporting evidence:* Likely most say "I search ANZCTR or apps separately, not integrated."
44. *Contradictory evidence:* If an existing feature (like a decision support alert) is widely used.

45. *Product impact:* If true, suggests a place for Heidi in clinician EHR (subject to interoperability constraints).

46. **Hypothesis: Specialist and coordinator roles overlap/confuse responsibility, leading to tasks falling through gaps.**

47. *Motivation:* Table shows many handoffs; unclear ownership can cause issues.

48. *Assumptions:* Teams sometimes assume "other person will do it" (e.g. will PI or coordinator call patient?).
49. *Participants:* Trial teams (PI, coordinators, research nurses).
50. *Method:* Process mapping workshops and interviews to identify role clarity. Pose scenarios (e.g. "Who calls patient to deliver test results?").
51. *Key questions:* Responsibilities of each role; how do they decide who does what when referrals come in?
52. *Supporting evidence:* If staff have differing views or gaps (e.g. PI thinks coordinator calls, coordinator thinks doctor calls).
53. *Contradictory evidence:* If roles are well-defined and followed.

54. *Product impact:* If true, Heidi's tracking or checklist functions might help define/alert roles.

55. **Hypothesis: Patients in regional areas prefer local trial participation if possible, but lack confidence that remote trials are accessible.**

56. *Motivation:* Teletrial success shows remote participation possible【60†L114-L122】, but patient perspective unclear.

57. *Assumptions:* Regional patients might distrust receiving care from “big city doctors”.
58. *Participants:* Rural/regional patients eligible for trials (e.g. kidney or cancer).
59. *Method:* Interviews/focus groups exploring awareness of teletrials and willingness to participate.
60. *Key questions:* Would you take part in a trial based in a city if it could be done locally? What are your concerns (travel, trust)?
61. *Supporting evidence:* Quotes in [60] show patients appreciate local involvement. Dr Carl above said remote places have new trial access【60†L168-L177】.
62. *Contradictory evidence:* If regional patients only trust being treated in person by specialists.

63. *Product impact:* If confirmed, emphasis on highlighting teletrial availability (and perhaps remote communication tools for patient reassurance).

64. **Hypothesis: Under-served patient groups (e.g. non-English speakers, elderly) have unique informational needs that are currently unmet.**

65. *Motivation:* The Arabic-speaking study【45†L61-L69】 implies culture/language is a barrier.

66. *Assumptions:* Standard consent and referral processes don’t account for these differences.
67. *Participants:* Patients from diverse linguistic/cultural backgrounds; maybe family/carers; clinicians serving them.
68. *Method:* Qualitative interviews on trial understanding, decision-making, and communication preferences in these groups.
69. *Key questions:* How did you find out about trials? Were materials understandable? Did family influence?
70. *Supporting evidence:* If patients cite confusion or family pressure as issues.
71. *Contradictory evidence:* If they felt supported (maybe via interpreter).

72. *Product impact:* High priority if true – Heidi might need features like multilingual outputs or culturally-tailored info (with oversight).

73. **Hypothesis: Trial site staff have low trust in unsupervised AI suggestions for clinical eligibility but are open to AI summarizing information.**

74. *Motivation:* New tech. Need to gauge acceptance of AI in workflow.

75. *Assumptions:* Staff want control over final decisions.
76. *Participants:* Coordinators, PIs, RGO staff, maybe ethics.
77. *Method:* Demonstrate mock-ups of “AI-flagged patients” or “AI summary”. Gather reactions.
78. *Key questions:* Would you trust an AI to shortlist patients? Or prefer it only to summarize data? What would make you trust it?
79. *Supporting evidence:* Likely skepticism about fully automated decisions.
80. *Contradictory evidence:* If some sites already use algorithmic matching (Torch recruit suggests some acceptance among innovators).

81. *Product impact:* If staff will only use AI as assistant, Heidi must ensure clarity that humans retain final control.

82. **Hypothesis: The most difficult stage for maintaining participant momentum is between referral and screening (scheduling diagnostics), where delays often occur.**

    - *Motivation:* Identified long lag here; patient health can change before screening.
    - *Assumptions:* Coordinators juggle many trials and external referrals can be slow.
    - *Participants:* Study coordinators across multiple trials.
    - *Method:* Workflow analysis: measure time from referral receipt to screening, interview coordinators on bottlenecks.
    - *Key questions:* What steps take the longest? How often do patients deteriorate or lose interest before screening?
    - *Supporting evidence:* Literature notes early attrition (19% die or hospice【16†L182-L190】) often due to delays.
    - *Contradictory evidence:* If coordinators report minimal delays (unlikely).
    - *Product impact:* If true, suggests tools for tracking and timely reminders (Heidi prompts) could be valuable.

Each hypothesis is structured to yield actionable insights. For example, if GPs cite lack of EMR integration as a barrier, Heidi's development might prioritize an EHR-connected trial search tool. If coordinators find AI summaries save time, we know which feature to refine. Research should ensure inclusion of diverse states and settings (e.g. interviews in both metro and rural sites) to capture variability. Findings will directly inform product features (e.g. trial alerts, referral templates, language support) and priorities (which broken processes to tackle first).

9. Recommended Primary Research Plan

Goals: To validate and refine the above hypotheses and to deeply map current workflows. A mixed-method study is proposed.

Priority participant groups:

- **General Practitioners**: Especially those with varied research involvement – from non-research practices to those in primary-care research networks.
- **Specialist clinicians** (e.g. oncologists, cardiologists) and **trial-site physicians/PIs**: Focus on those involved in trials.
- **Trial-site staff**: Study coordinators, research nurses, ethics/RGO officers. They understand internal processes.
- **Patients / Participants**: Cancer or chronic disease patients who have been referred to a trial (successful or not). Also caregivers of children if relevant.

Sample composition:

- Aim for diversity: at least 5-7 from each actor category, across different states (NSW, QLD, Vic, WA) and urban/rural. Include sites with high trial volume and smaller sites (rural hospital with teletrial). For patients, include some CALD backgrounds to test cultural hypotheses.
- Sampling criteria: For patients, select those who are in or recently completed screening (to recall journey). For clinicians, include some early-adopters (site investigators, research-active) and some

community doctors (GPs). Use professional networks (e.g. GP divisions, trial networks) for recruitment.

Interview topics:

- *Gaps from desk research:*
- How do you currently find out about trials? (GP vs specialist vs patient perspective)
- Describe a recent case: how was a patient identified and referred? What tools were used?
- What documents or systems do you use? (EMR, spreadsheets, etc.)
- What are the pain points at each stage (time delays, lost info, patient confusion)?
- Attitudes to technology: Would alerts or AI summaries be helpful or worrisome?
- *Workflow observation:* Where possible, accompany a trial coordinator or GP for part of a day to see actual referral work (notes anonymized), or have them walk us through a typical case (using any forms/templates they use).
- *Artefacts:* Request access to de-identified sample referral letters, screening logs, or SOPs. Observe how referral forms are stored/tracked. If CTMS or EDC screenshots can be shown (dummy data), that reveals systems used.
- *Patients:* Ask patients to describe their experience: how they learned of the trial, what their doctor told them, what paperwork they completed, and how the trial staff communicated with them. Identify confusion or unmet information needs.

Contextual inquiry:

- Shadow a trial coordinator during the referral-processing stage to record steps taken (e.g. picking up calls, checking mailbox, data entry).
- Observe an ethics/RGO office handling a clinical trial application (with permissions) to see approvals workflow (though outside referral path, it informs site start-up delays).

Ethical considerations:

- Patient confidentiality: All patient data discussed must be de-identified. Obtain ethics approval for interviews, especially with patients.
- Consent for observation: make sure consent is obtained before shadowing or reviewing any records.
- Avoid undue influence: Ensure patients understand interviews are voluntary, separate from any care.
- Privacy in AI context: Ask specifically about comfort with data use in hypothetical AI tools.

Artefacts to request:

- Examples of trial referral forms and the hospital's site-specific forms.
- The template of a consent form or patient info sheet (for content clarity).
- The hospital's screening log or CTMS screenshots (de-identified) to see data fields.
- Any local guidance documents (e.g. site SOP for trial enrollment).

Topics beyond desk scope:

- **Real error rates:** e.g. how often are patients lost to follow-up?
- **Informal practices:** E.g. does "word of mouth" still recruit patients? Are there community advocates?
- **Non-documented delays:** e.g. "What typically takes months to complete in your process?" – not in literature.

- **Stakeholder incentives:** E.g. how might clinicians feel about AI prompts for trials.

Synthesis method:

- Thematic analysis of interviews, mapping onto the journey framework.
- Identify process variations by site type (tertiary cancer center vs rural hospital).
- Use journey mapping (with swimlanes) to visualize the actual flows and where our earlier model needs adjusting.
- Build personas or user stories for each actor to capture needs and contexts.
- Quantify where possible: e.g. coordinator reports average days referral-to-screening, percent incomplete referrals.

This initial study would validate where automation or support could best help, reveal nuances (e.g. doctor–patient communication preferences) and check for missing stakeholders (e.g. pharmacy? healthcare insurers?). It would set priorities for Heidi's development, ensuring solutions align with real-world needs and constraints.

10. Sources

1. **Australian Clinical Trials (Australian Government)** – *"Referring a patient to a clinical trial"* (20 Oct 2023) – Government site with referral guidelines for healthcare providers【18†L52-L57】. *Sector: Government; Jurisdiction: National.* Directly details clinician steps to find trials and the coordinator's role. (Source type: Official portal; limits: general guidance, not a workflow audit.)

2. **Australian Clinical Trials (Australian Government)** – *"Sponsoring a clinical trial in Australia"* (7 Nov 2023)【31†L65-L73】. Defines sponsor responsibilities (approvals, ethics, insurance). *Sector: Government; Jurisdiction: National.* Confirms sponsor must obtain approvals and manage legal aspects. (Source type: Official guidance.)

3. **Scientia Clinical Research (Private Health Service)** – *"Oncology Trials – Referrals for Referrers"* (accessed 2026)【13†L1-L9】【13†L19-L22】. Instructs GPs/patients to submit detailed referral letters (with scans, bloods, etc.) for review. *Sector: Private research company; Jurisdiction: NSW.* Evidence of site-level referral process (likely a common model). (Source: Corporate guidance; single-organization observation; limitations: cancer-specific.)

4. **Michaud et al., Communications Medicine (2026)** – *"Progress and challenges in expanding access to clinical trials in pancreatic cancer"*【16†L205-L213】【16†L219-L227】. A medical review noting low trial offer rates (27% offered, 20% enrolled), reliance on clinician networks for referrals, and 56% of patients lacking local trials. *Sector: Research; Jurisdiction: Mixed (references Australian data)*. Provides corroborated patterns that trial identification is inconsistent and referrals informal. (Source: Peer-reviewed; evidence level: mixture of Aus registry data and international studies.)

5. **Australian Department of Health** – *"Who can participate in a clinical trial"* (undated)【6†L21-L28】. Outlines patient eligibility rules (citizenship, consent, etc.). Mentions government doesn't refer individuals but encourages health professional guidance. *Sector: Government; Jurisdiction: National.*

Highlights that patients are guided to talk to clinicians for trial info. (Source: Gov't info; evidence: patient guideline.)

6. **ABC Health Report (interview transcript)** – *"Clin Trial Refer app connects patients and doctors with clinical trials"* (Aug 2014)【22†L137-L146】【22†L203-L210】. Interviews with NSW clinicians describing the haematology trial app and referral pathway (GP to specialist). *Sector: Media (ABC); Jurisdiction: NSW/ACT.* Provides example of how an app improves discovery and confirms the common route is GP referral to a specialist. (Source: Public media; evidence: expert anecdote.)

7. **VCCC Alliance – Principal Investigator Roles** – *"Principal Investigator"*【24†L263-L272】 (date unspecified). Defines Site PI duties: protocol compliance, approvals, participant welfare, reporting. *Sector: Nonprofit (Victorian cancer alliance); Jurisdiction: VIC.* Direct evidence of PI responsibilities in Australian cancer trials. (Source: Institutional guidelines; direct evidence.)

8. **VCCC Alliance – Study Coordinator Roles** – *"Study Coordinator/Research Nurse"*【28†L269-L277】【28†L305-L313】 (date unspecified). Describes coordinator liaising between PI, sponsor, ethics; handling feasibility, ethics submissions, screening, data entry, adverse event reporting. *Sector: Nonprofit; Jurisdiction: VIC.* Direct evidence of coordinator tasks in trial conduct. (Source: Institutional guidelines; direct evidence.)

9. **VCCC Alliance – Barriers in trials** – *"Challenging barriers in the clinical trials landscape"* (12 May 2022)【54†L344-L352】【54†L355-L363】. Discusses trial complexity and patient burden: multiple hospital visits and narrow criteria reduce participation, especially for rural/regional. Introduces registry and teletrial methodologies as solutions. *Sector: Nonprofit; Jurisdiction: VIC.* Supports issues of travel burden and eligibility complexity, and notes novel trial models. (Source: Community news article; evidence: expert commentary.)

10. **Clinical Excellence Queensland** – *"Strengthening Remote Healthcare Through Trial Participation"* (June 2026)【60†L101-L109】【60†L114-L122】. Case study of a teletrial kidney trial in remote Queensland. Notes 90% of trials urban, teletrial model with primary and satellite sites, and QRCCC support to improve rural access. *Sector: Government; Jurisdiction: QLD.* Direct evidence of teletrial approach and motivation to reduce travel burden. (Source: Gov't showcase; evidence: case study.)

11. **University of Melbourne** – *"Torch Recruit: bringing clinical trials to regional patients"* (Mar 2023)【36†L30-L39】【36†L43-L47】. Describes an algorithmic platform for GPs to identify trial-eligible patients from EMR data (for a liver cancer study). Emphasizes efficiency vs "cold calling GPs". *Sector: University; Jurisdiction: National.* Evidence that structured EHR data can feed automated matching. (Source: Institutional case study; evidence: project description.)

12. **Salim et al., Trials** – *"Healthcare professionals' perspectives on barriers to trial participation among Arabic-speaking patients in Australia"* (Jun 2026)【45†L61-L69】. Qualitative study: HCPs cite limited consult time, restrictive criteria, lack of translations as barriers; enablers include interpreters, family support. *Sector: Academic (Flinders); Jurisdiction: National.* Highlights language/cultural barriers and structural time constraints affecting trial access. (Source: Peer-reviewed; direct evidence for CALD patient issues.)

13. **MJA Editorial (Ansell)** – *"The go-between: general practitioners and clinical trials"* (Sept 1999)【43†L42-L51】【43†L89-L97】. Discusses GPs' pivotal role and difficulties (lack of trial knowledge, time constraints, patient concerns about trials). Advocates better GP information and involvement. *Sector: Medical journal; Jurisdiction: National (Australia).* Illustrates GPs' attitudes and issues in trial referral; though dated, remains relevant. (Source: Peer-reviewed editorial; evidence: GP survey results.)

14. **NT Health – Research Governance** – *Research Governance policy* (date unknown)【49†L63-L71】. Outlines RGO role: ensuring ethical compliance, site PI delegation, SSA requirements. Requires both HREC and RGO approval before any NT Health research starts. *Sector: Government (NT); Jurisdiction: NT.* Evidence on governance process: SSA needed, RGO duties. (Source: Govt policy; direct evidence.)

15. **VCCC Alliance / CRDO Glossary** – *Glossary definitions* (Melbourne Children's) – (accessed via search) – Defines CRO, etc. Not opened, skip.

16. **ANZCTR / Australian Clinical Trials** – *Search functions and registries* (general). We did not cite ANZCTR website directly, but info is aggregated in [18] and [22].

17. **Other**: Some site SOPs and state guidelines were inferred (e.g. SSA requirement at UQ [48†L7-L10]). Explicit citations were mainly from [24], [28], [31], [18], [60], [54], [36], [45], [43], [22], [13], [16].

Limitations: Many insights come from oncology-focused sources or case reports. Evidence for primary care, pediatric, or non-cancer contexts is sparse (we infer these areas). Vendor sources (ClinTrialRefer app, Omico) are illustrative but may overstate impact. The draft hypotheses and workflow rely partly on logical inference where specific Australian data were not found. Future research should validate these findings in diverse trial contexts.
