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# Strengthening Patient Engagement on Clinical Trials

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## Session summary

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- Patient recruitment is expensive but inefficient
- Retention and Adherence are key problem areas
- Patient-centric trial design and execution can help improve engagement

# Recruitment merits focussed efforts and budgets

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- Multiple channels
  - Physician referrals
  - Advertising and direct mailings
  - Internet registration
  - Patient organizations, esp for biologics & orphans
- Consumes up to a third of total study costs
  - Tighter regulatory expectations
  - Enrollment challenges and inefficiencies

## However, enrollment is a difficult and expensive process

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- Awareness about clinical trials and success stories
- Public perceptions about big pharma and drug safety
  - 14% Americans see pharmacos as “honest” \*
  - 41% Europeans see trial patients as “guinea pigs” \*
- Physicians reluctant to refer patients or conduct trials
  - <5% of US physicians participate in trials
  - 38% of physicians do not conduct a second trial \*

\* Harris Interactive, Tufts Center

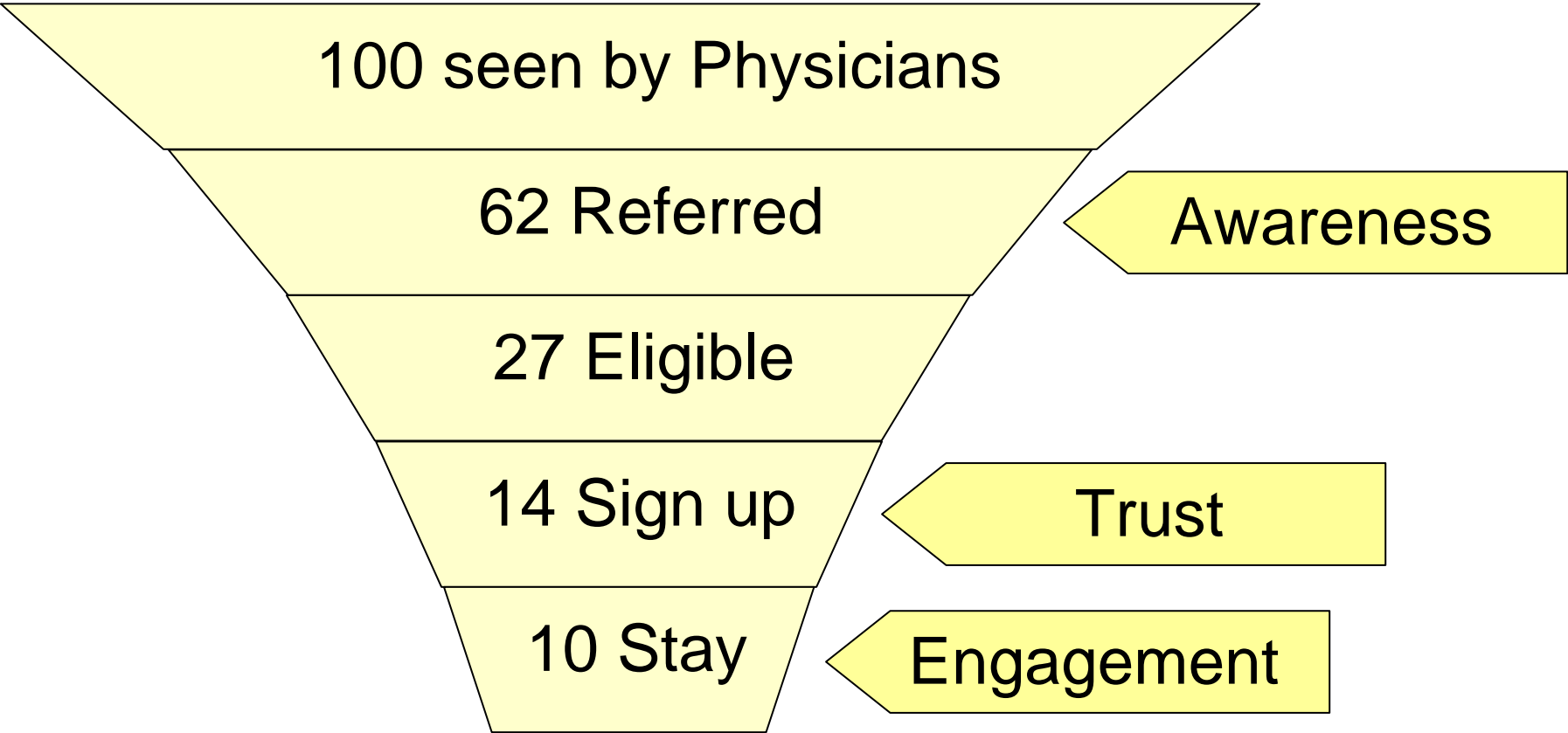
## However, enrollment is a difficult and expensive process (2)

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- Patients increasingly ineligible for trials due to multiple chronic conditions
- Trust gap due to jargon-heavy Informed Consent
- Poor collaboration across Design and Front-line silos
- Enrollment delays impact over two-thirds of all trials
- Lower numbers => more sites => higher costs

# Representative numbers from oncology trials

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\* Journal of Clinical Oncology, 2001, 19(6) 6

Post the huge upfront investment in recruitment,  
returns are often unimpressive

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Only ~5% of recruited patients provide  
conclusive results useful for a dossier \*

– Two Root Causes –

**Retention** and **Adherence**

## Retention usually doesn't get adequate focus

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- Patient drop-out rates are nearly one-third \*
- Under-appreciation of volunteer patients
  - Only one-fifth hear back from sites \*
- Poor communication of trial outcomes and research contribution to participating patients
  - Missed opportunity to cultivate patient advocates
- Excessive travel to investigator sites

\* FasterCures

## Adherence to protocol is a well-known challenge

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- “Drugs don’t work in patients who don’t take them.”
  - C Everett Koop, 13<sup>th</sup> US Surgeon General
- “Keep watch also on the faults of the patients, which often make them lie about the taking of things prescribed.” – Hippocrates

## For in-market drugs, non-compliance has a huge impact on patient health as well as drug economics \*

- ~80% fill rate for new prescriptions
- ~30% of prescriptions consumed as directed
  - Six-month compliance is better: 40 to 80% for chronic diseases
- ~\$30 billion in lost drug revenues
- Poorer health outcomes and higher medical costs

# Clinical trials have to cope with similar challenges

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- Adherence at 40 to 80 % for chronic ailments \*
- Inadequate patient awareness and motivation
  - Adverse reactions or lack of therapeutic impact
  - Behavioural or lifestyle issues
- Measurement difficulties
  - Patient diaries are used in a fourth of all trials but only 5-10% are electronic \*
  - Pill / prescription counts help but aren't adequate
  - Patient surveys have limitations

\* New England Journal of Medicine, Bio-IT World, IDC

## For patients recruited in developing countries, there may be additional barriers to adherence

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- Low educational levels
- Local cultural factors
- Geographic spread and access to medical facilities
- Under-informed consent
- Fewer investigators and heavier schedules
- Lack of training for site staff

# A patient-centric approach can improve retention as well as adherence

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1. Better protocol design, site assessments and study planning
2. Patient-centric product design
3. Strong engagement during the early days
4. Ongoing connect between patients and sites
5. Availability of multi-channel patient support
6. Smarter use of IT to increase effectiveness and drive down costs

# 1. Better protocol design, site assessments and study planning

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- Incorporate recruitment-related inputs from front-line staff into protocol design and study planning
- Ensure “closed-loop” feedback to design team from CROs and other externals responsible for recruitment
- Avoid unrealistic and time-consuming expectations from patients
- Keep dosing simple
- Invest in site assessment, selection and support

## 2. Patient-centric product design

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- Packaging is critical. Prioritize patient-friendliness over production efficiency.
- Use blister packs with visual aids, instead of bottles
- Avoid large capsules (e.g., over-encapsulation for double-blind trials)
- Design labels in line with patient information needs
- Evaluate RFID for better compliance measurement

### 3. Strong engagement during the early days

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- Facilitate quick and easy matching of clinical trials with patients (e.g., EmergingMed)
- Use well-articulated Informed Consent to educate patients as well as gain trust
- Invest in clinical education teams to coach patients on the disease and to facilitate treatment adoption
- Telephonic nursing support in the initial stages

## 4. Ongoing connect between patients and sites

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- Promise and provide state-of-the-art medical care
- At times, take the site to the patient. Provide personalized at-home support when needed.
- Encourage direct communication between patients and sites. Recognize efforts by study coordinators.
- Frequently communicate the big picture. Report overall progress and outcomes from the study.
- Sustain ongoing awareness through newsletters
- Nurture patient ambassadors to spread the word

## 5. Availability of multi-channel patient support

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- Establish patient helplines using qualified personnel
  - Managing side effects of the therapy
  - Help with complex drug delivery mechanisms
  - Counselling and emotional support
  - Insurance and reimbursement queries
- Set up multi-channel reminders (e-mails, SMS, IVR, phone calls) for medication, physician appointments and record-keeping

## 6. Smarter use of IT to increase effectiveness and drive down costs

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- Streamline patient engagement processes across trials, with a common but customizable IT platform
- Provide patients online access to own records and to summary information on the overall trial
- Create online patient support networks, including peer-to-peer mentoring
- Use Electronic Patient Diaries, instead of paper
- Every measure or tool is not necessary for every trial. Adopt a subset in line with trial-specific needs.

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## Questions & Feedback

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