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Feasibility Solutions to
Clinical Trial Nightmares



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What do our Project Managers dream about?

Protocol rejection

Low investigator acceptance



Slow start up

Poor recruitment



How can feasibility help?

- Early, detailed feasibility can provide solutions to all these nightmares!
- BUT.....
- More commonly in our industry we rely on feasibility conducted during the 10 day proposal process to provide the strategy and planning for multi million dollar studies and programs!



It's never too soon for feasibility for.....

Protocol Development

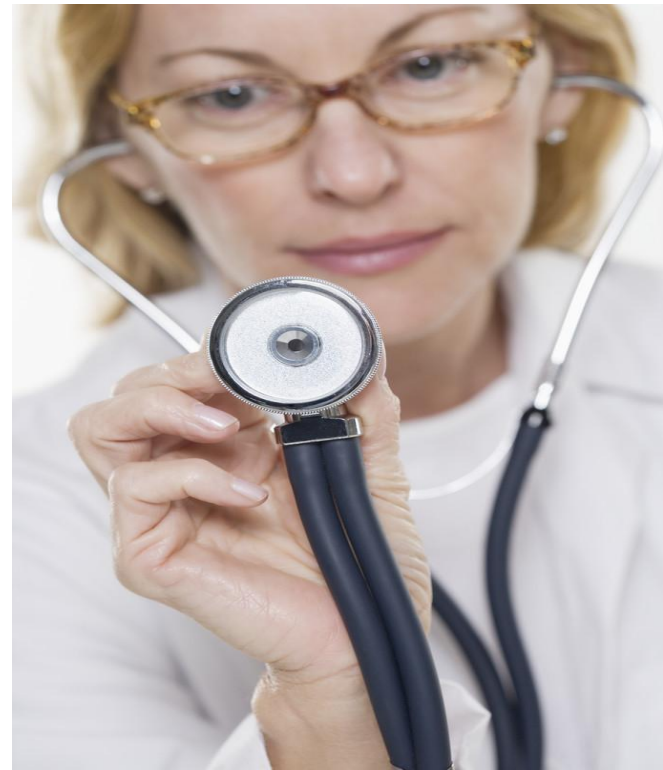
Country & site strategy

Recruitment planning



Protocol development

- Placebo control
- Washout periods
- Patient assessments tools
- Specialist equipment
- Invasive procedures
- Too many visits
- Complex diary data





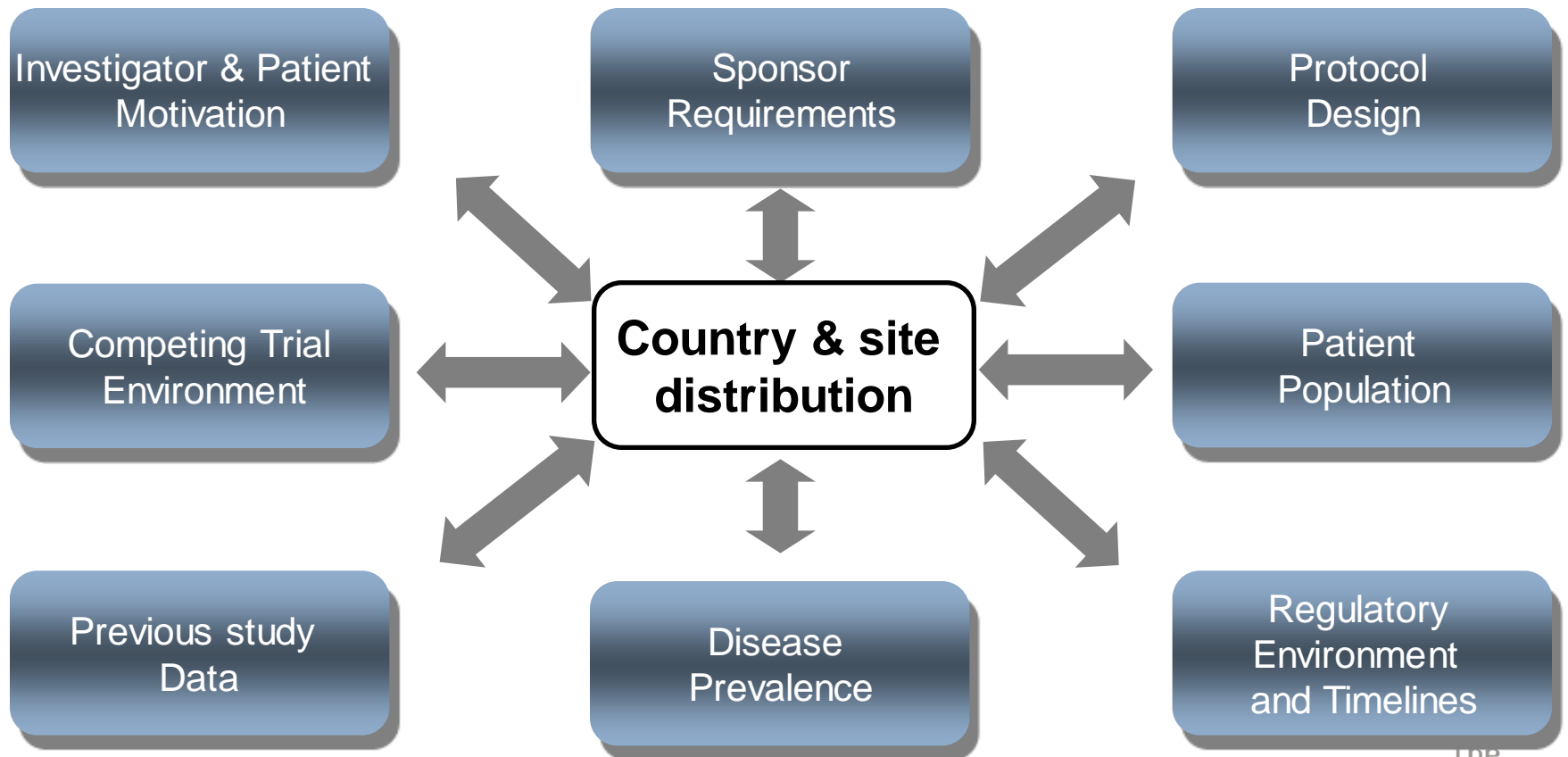
Avoid protocol rejection / amendments

- Justify study design
- Explain rescue medication and patient evaluation in detail
- Match protocol with standard of care
 - Assess investigator common practice for diagnosis, treatment and long term evaluation
- Take care when including labs for paediatrics
- Consider that patients have a life outside of the study



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Successful strategy development includes





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Investigator and patient motivation

What motivates.....

Investigators

1. Scientific interest/recognition/publication etc.
2. Benefit of better treatment options for patients
3. Lower costs of treatment for site and/or patients
4. Appropriate fee
5. Funds for improved equipment/facilities

Patients

...to join a study

1. Access to relief of symptoms
2. Long term treatment of illness
3. Regular check ups and contact with medical staff (TLC)
4. Reduced treatment or clinic attendance costs
5. Education and information about their condition/study/treatment options
6. Meeting others with same illness



Recruitment planning

Identify the ideal site profile

Balance recruitment time with site numbers and distribution

Know your target patient population

Data collection is key





Questionnaire lottery

Feasibility data isn't
just about estimated
recruitment rates from
investigators

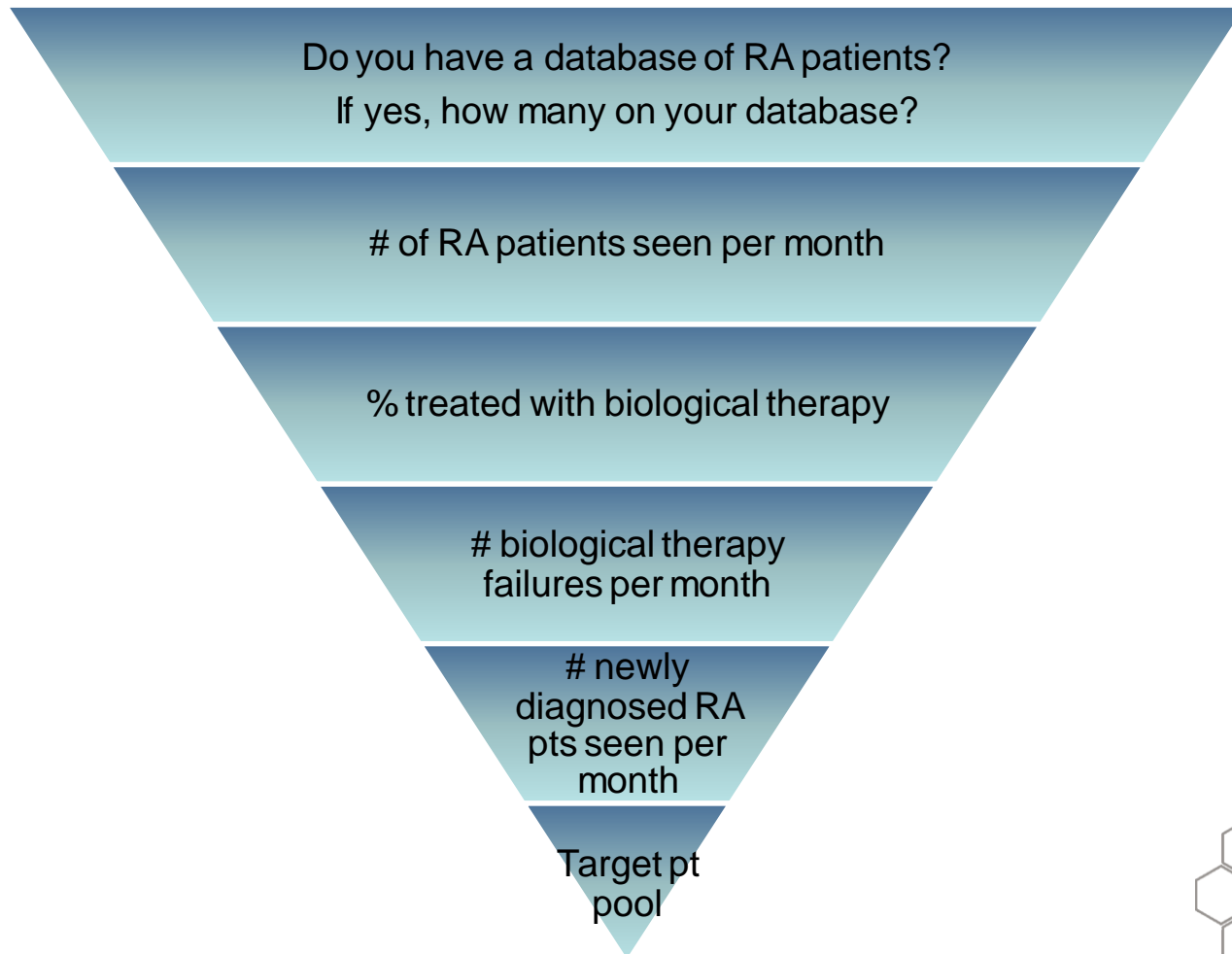




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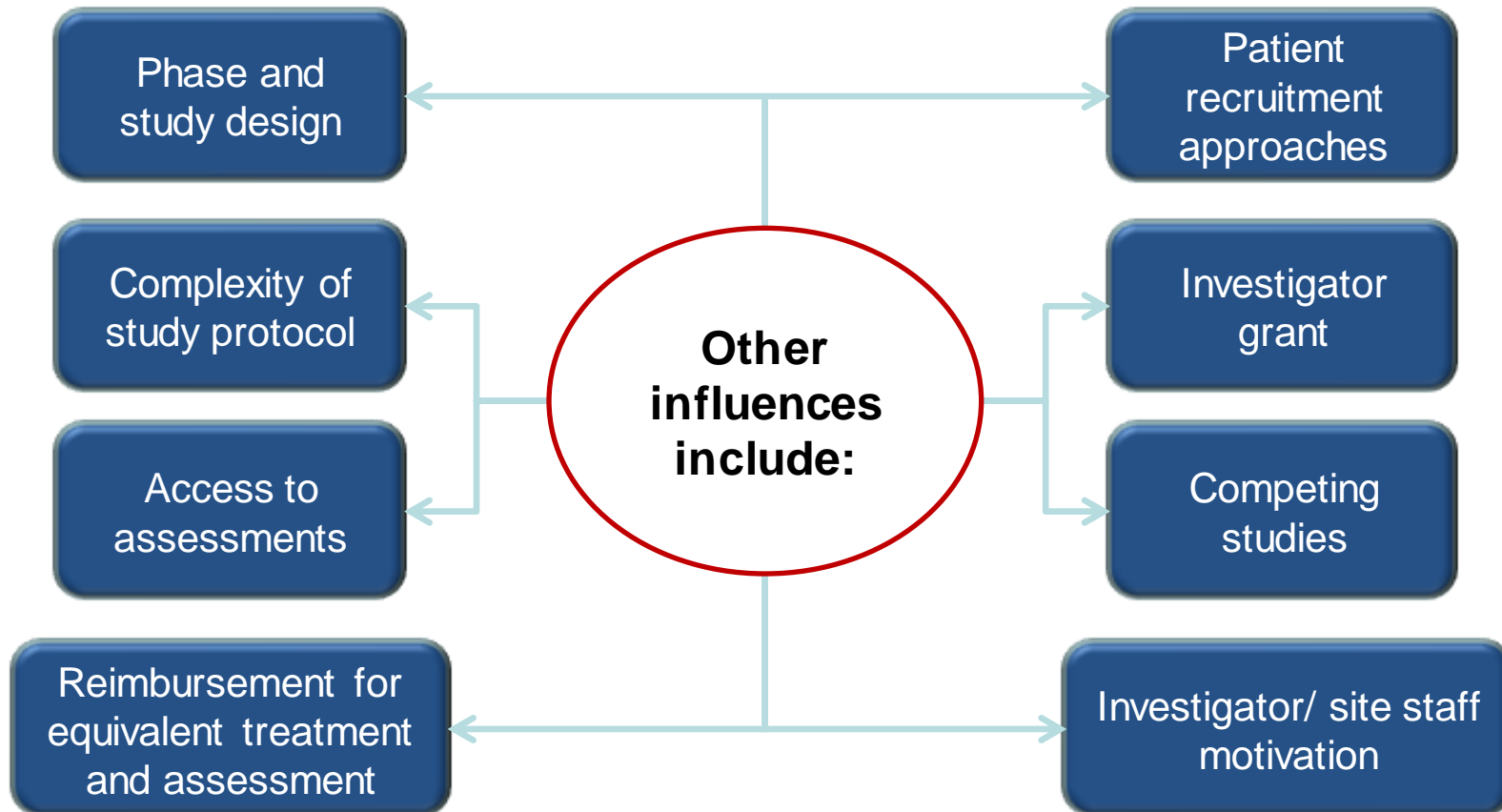
The patient funnel

RA patients who haven't had biological therapy in last 3 months





The patient funnel isn't the complete story...





Feasibility in practice – A case study

Phase 2, placebo controlled study requiring ~800 FI patients with minimal scar tissue with moderate to severe FI symptoms

Feasibility:
6 weeks
(+2 weeks KOLs)

**Protocol
update:**
4 weeks

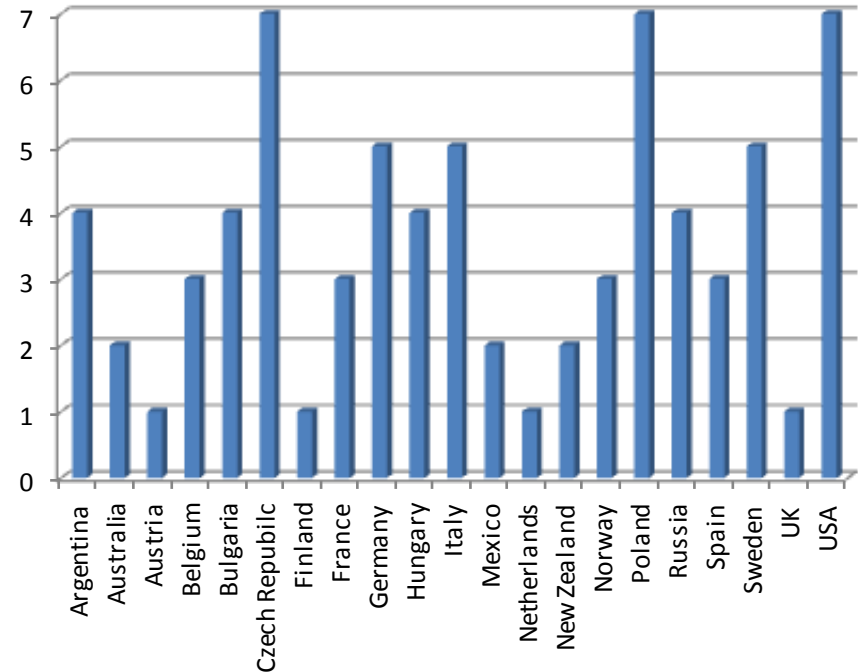
**Site
identification:**
4 weeks



Feasibility summary

- Data from 104 sites in 21 countries globally
- Highest level of interest found in Europe
- Diverse range of physicians and healthcare professionals see these patients
- Limited previous study activity mainly in devices, injectables and nerve stimulation
- Many patients are not actively treated in the sites, many are in other institutions, healthcare facilities or in many cases not seeking medical advice but self medicating

Interested sites





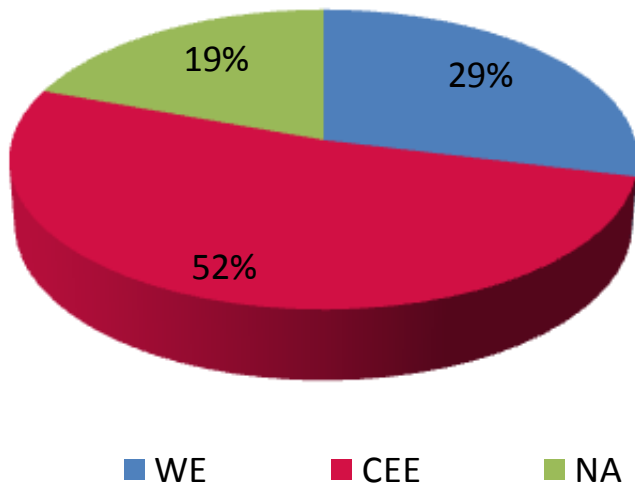
Protocol updates following feasibility

Change of FI assessment score	Reduced patient numbers
Reduced post screening run in period	Patient evaluation procedure modified
Modification to extended first visit	Refined diary data to be collected



Country selection

Regional % split of patients

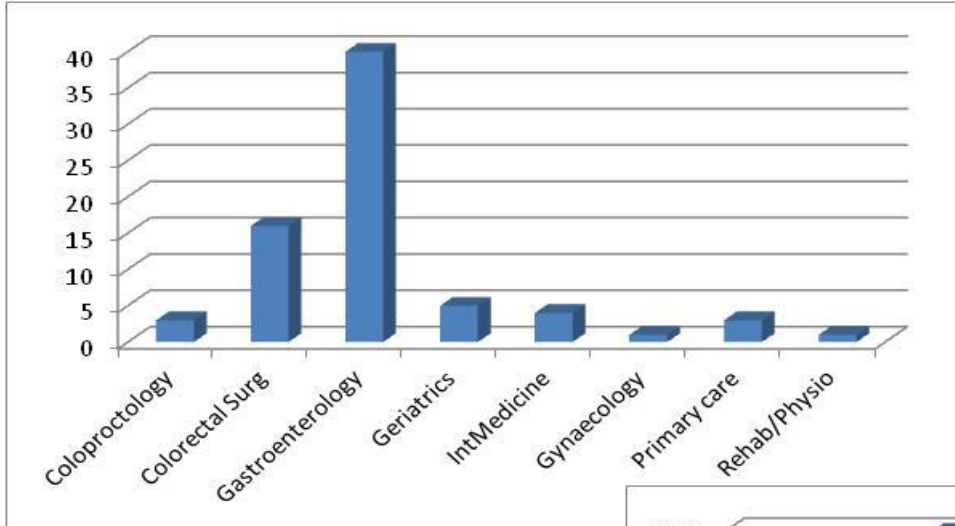


- Five regions assessed but low interest from AP & LA
- Countries selected based on level of interest and recruitment potential
- Main response from WE & CEE
- US included for marketing purposes
- Recruitment expected to be higher in CEE based on feasibility results
- Majority of sites confirm they would need outreach/advertising to support recruitment



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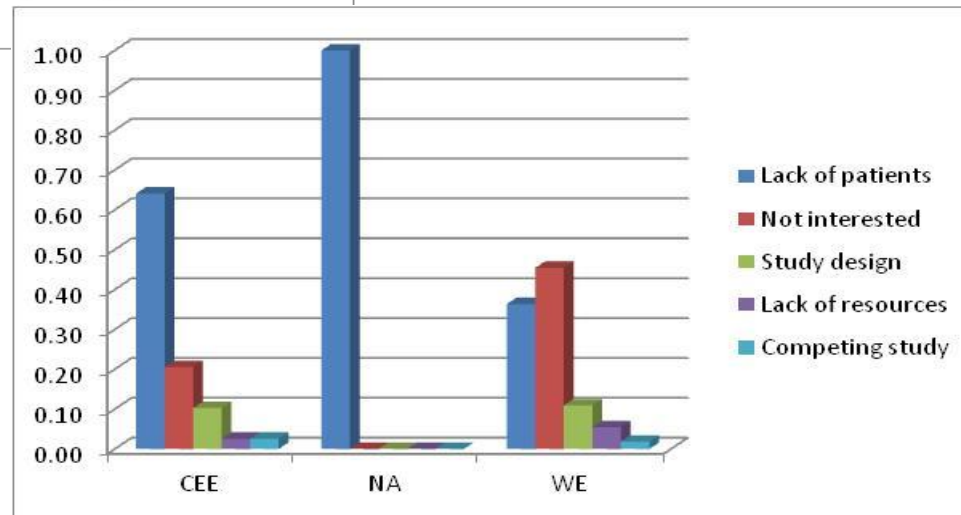
Build patient recruitment strategy on feasibility data and local knowledge



Gastroenterologists are the ideal site but many others see these patients

Main reason for declining = lack of patients...

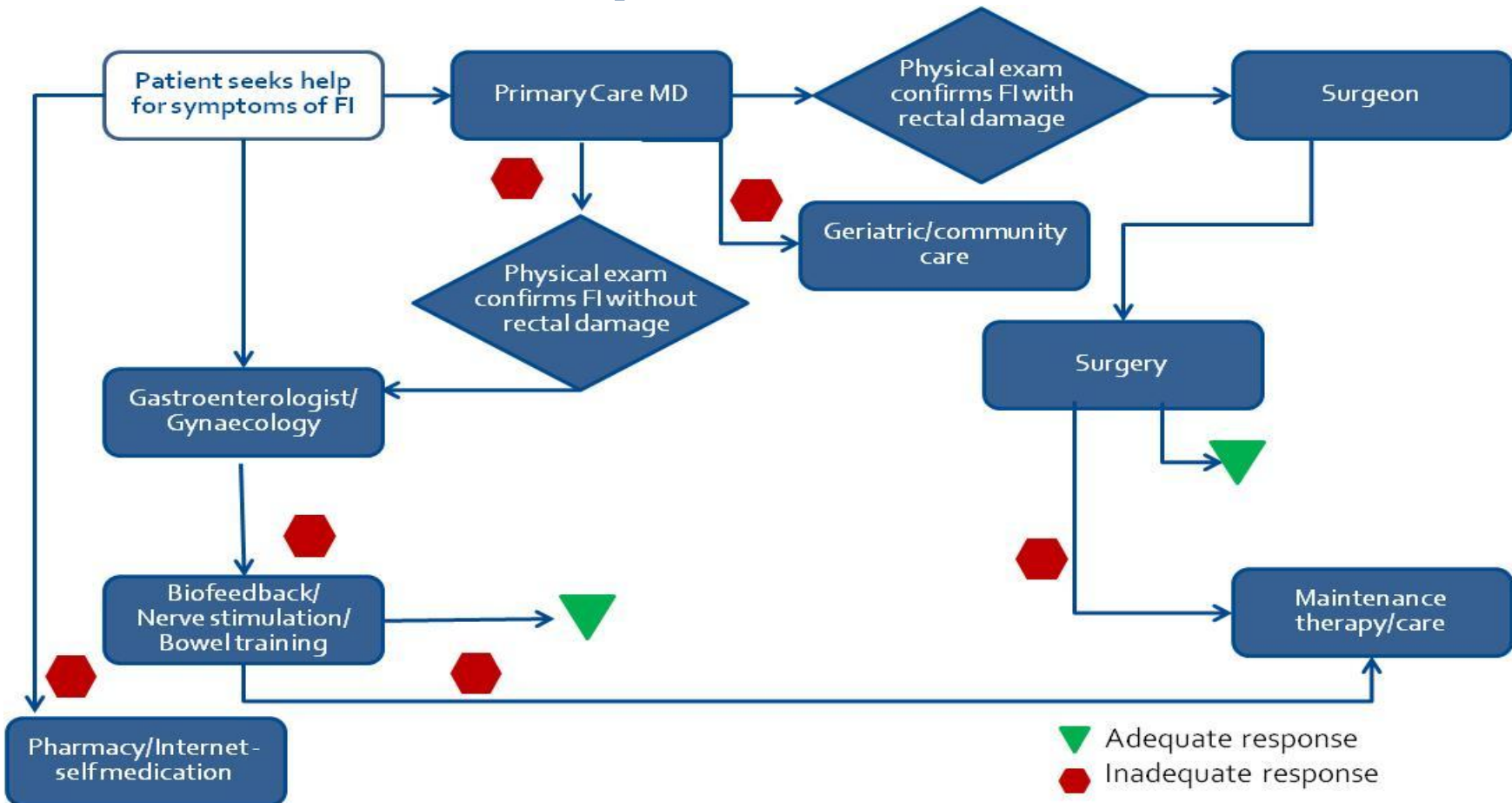
...but could sites be interested with supported outreach and referral



Case Study: FI



Understand the FI patient flow



▲ Adequate response
● Inadequate response





Patient recruitment challenges identified

- A topic not openly discussed – quite frankly it's embarrassing
- Our patient population is hidden – only 1 in 8 present
- Practicalities of travelling to sites for visits – limited reach of patient catchment area
- Overcoming specific hurdles of protocol at the crucial consent stage
- Intrusive exams
- Treatment free run-in period
- Long first treatment visit in clinic
- Placebo controlled study
- Significant portion of population potentially excluded due to presence of cardiovascular conditions



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Proposed 3 tiered approach to material development

Essential items

Identity, tools for site, direct to patient outreach & referral

Targeted Media campaign

Press/radio advertising in selected countries, washroom advertising, website and targeted mailing kit

Nice to have

Mini protocol, pre screen checklist, visual informed consent guide, patient brochure, conversation guide, print advertorial, banner advertisement referral fact card & loyalty and retention items



Case Study: FI



20: 28/11/2011



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**No more nightmares...feasibility can lead to
much sweeter dreams...**

