How to be successful in the three I's:

Industry and Investigator Interactions

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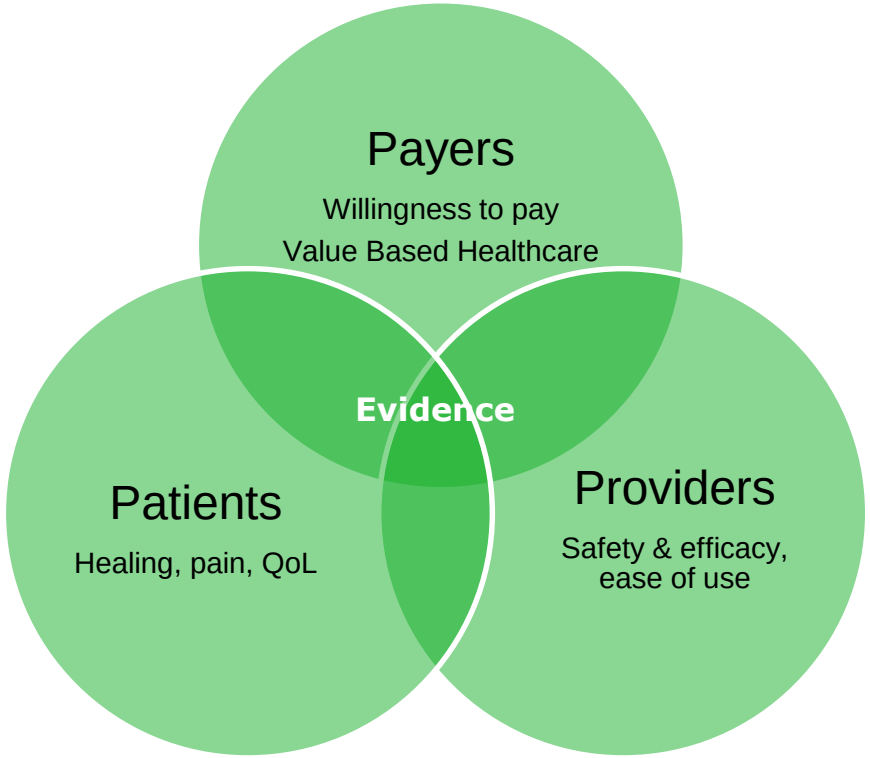
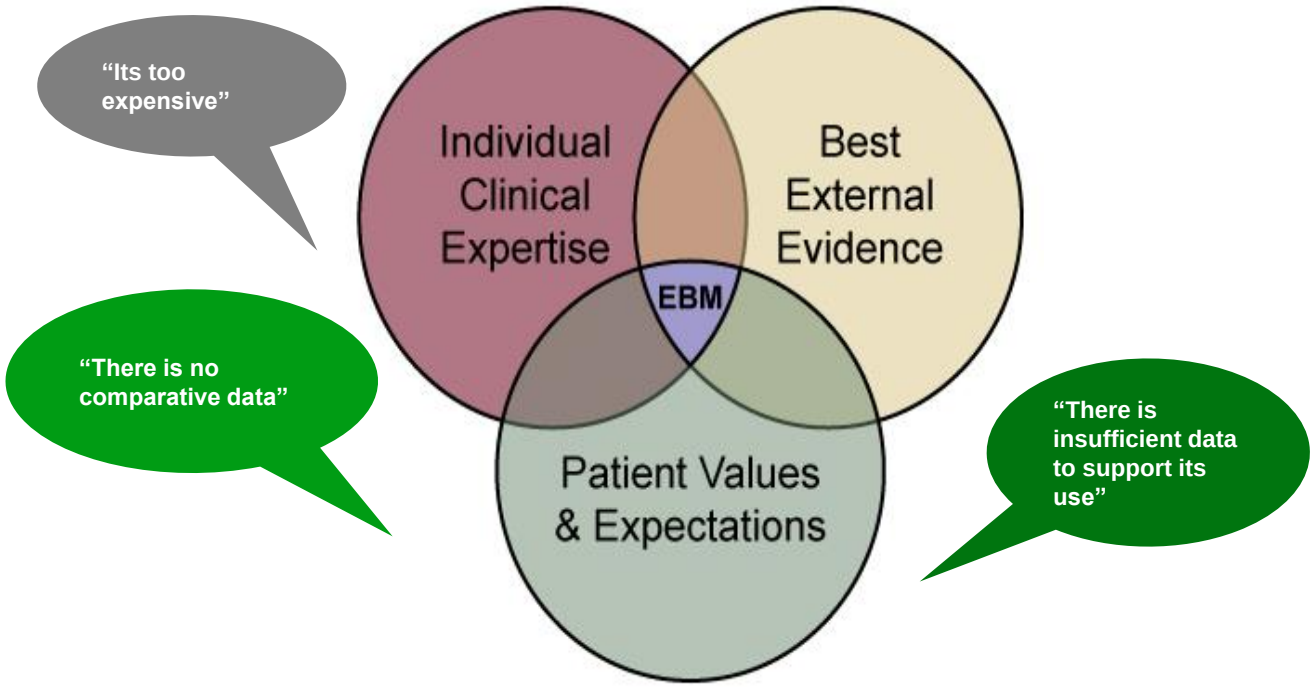
The External Stakeholders

There is a dilemma in producing clinical evidence in the ever evolving area of wound care in a timely manner, which addresses the needs of all stakeholders. Often these demands are conflicting.



Evidence Based Medicine



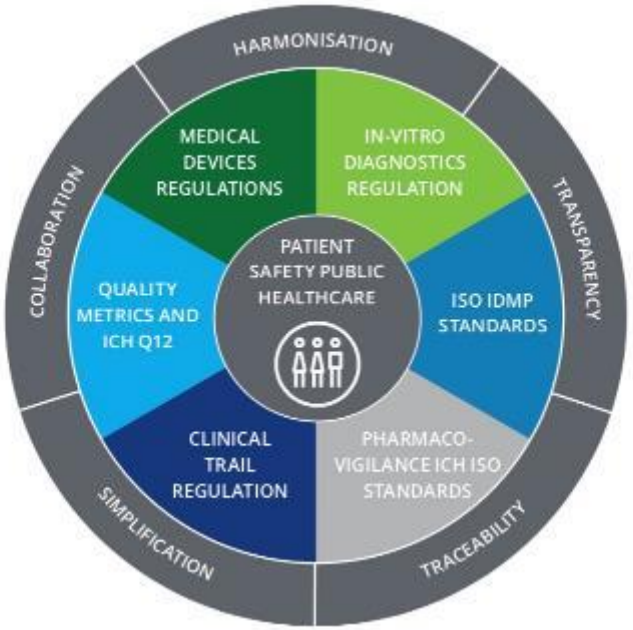
Ragnar Levi and Christina Alvner,
Medical Science and Practice 1998, 2:1

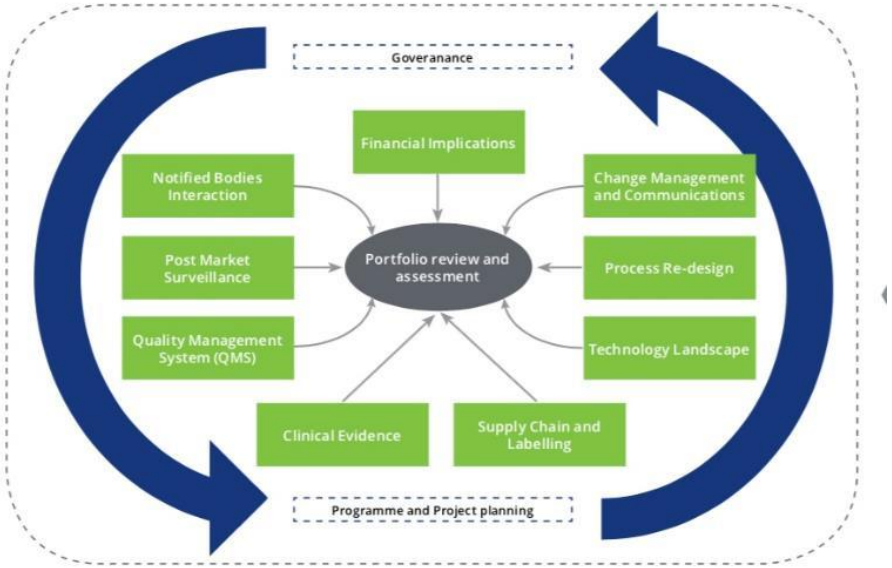
Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.[1]

Caveat: Until evidence is established, practice cannot be frozen

1. Lancet. 1995; 346:407-410. Inpatient general medicine is evidence based. Ellis, J et al.
2. Br J Surg. 1997; 84:1220-1223. Hoes, N et al

Higher demands on evidence: The new EU medical device regulation (MDR)





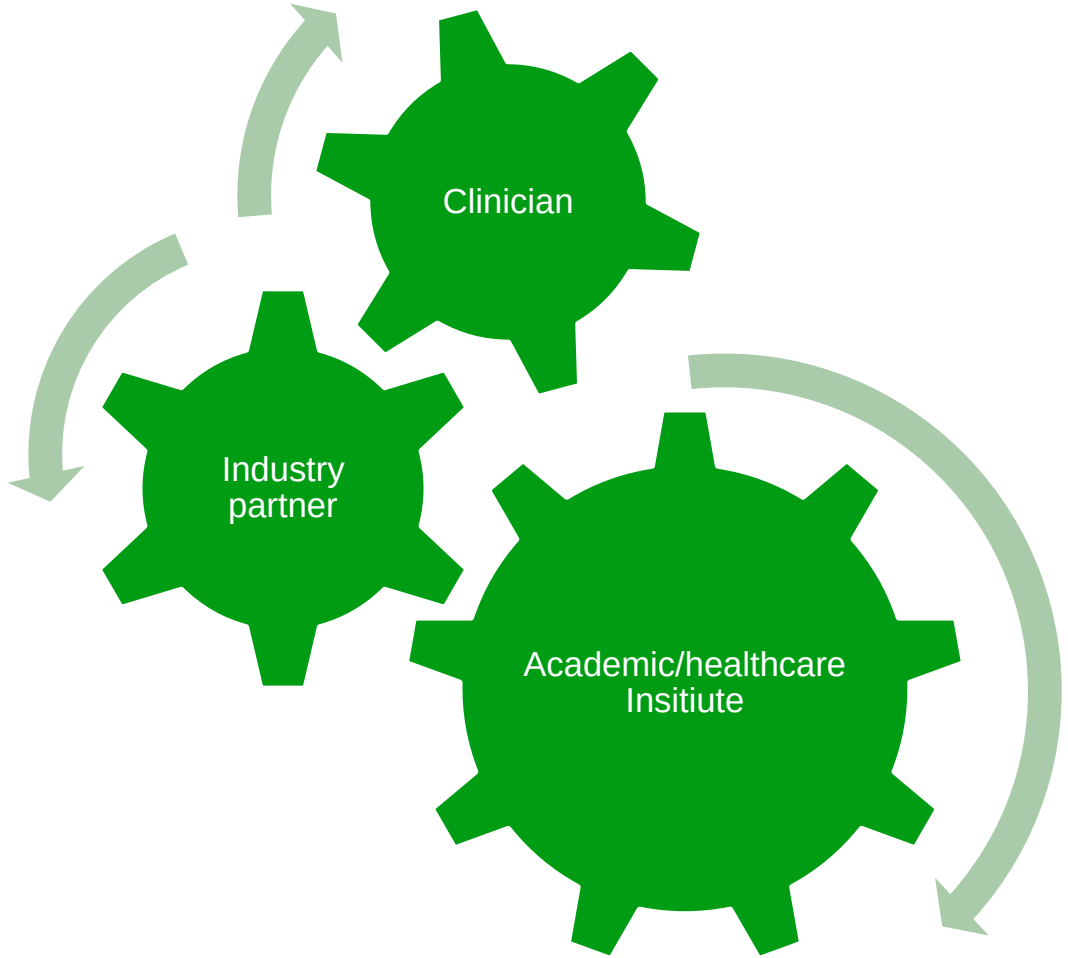
- April 5th 2017: The Medical Device Regulation (MDR) was adopted by the European Union
- The MDR officially replaces the Active Implantable Medical Device Directive (AIMDD, Council Directive 90/385/EEC and the Medical Device Directive (MDD)
- The MDR also includes various sections closely aligned with ISO 14155:2011 (Clinical Investigation of MD for human subjects; Good Clinical Practice; and Declaration of Helsinki)

So how do we proceed in this ever evolving world

All require some level of collaboration between investigator and industry to be successful

Data is key, but studies should not be evaluated in isolation

Its three-way….



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Them and Us mentality does not work!

Strengths

- Increased credibility and independence of data
- Greater and broader portfolio of data
- Transparency of results
- Clinicians input and co-ownership of protocol, data analysis, interpretation and publication
- Access to relevant patient population

Opportunities

- Clinician network access
- Strong relationships build on clear objectives and aligned goals.
- One positive experience leads to repeat experiences
- Greater implementation of the findings via peer to peer network
- Academic funding for research is in a constant decline
- Personal development

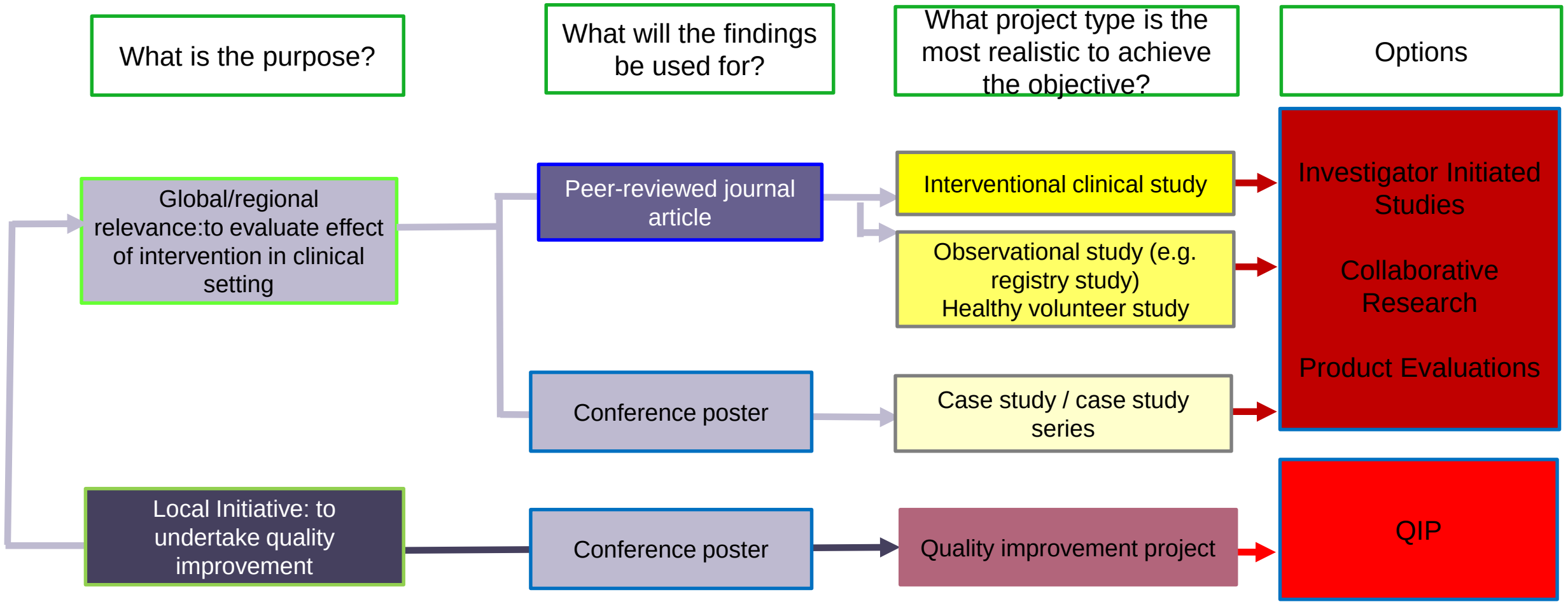
Weaknesses

- Investigator must have the experience, resources and time
- Problems arise when objectives and goals are not aligned upfront or change over time
- Is collaboration with the company or a specific individual within the company?

Threats

- Communication!
- Transparency in terms of healthcare compliance
- Lack of control for industry partner
- Timelines can be timeless
- Company strategy changes
- Perception that investigators are simply an extension of the industry partner

So what are the collaborative research options?



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Evidence type	Objective	Generated data type	How can data be used?	Complexity (time + money)
Product Evaluation	Check practical product properties in market (questionnaires)	Simple subjective, non-clinical data	Primary for internal use at both facility and by industry partner	Low
Clinical case reports/series	Capture real life use of (new) products	Real life clinical / economic data from a small group of patients	Non-peer reviewed outputs as conference poster or symposium, External use e.g. marketing material, communication, education	Medium (may need research ethics approval*)
Quality improvement project (QIP)	Change clinical practice and show improved outcome	Clinical / economic data on improved outcome (i.e. before and after)	Non-peer reviewed outputs, e.g. conference poster, symposium, educational material External use e.g. marketing material, communication, education	Medium/high (may need for ethical approval)
Investigator-initiated study (IIS)	Test the hypotheses of customers Needs to be externally initiated e.g. by physician	Data related to clinical effectiveness, safety, cost-effectiveness - non-comparative or comparative	Peer-reviewed publication (journal article) Non-peer-reviewed outputs, e.g. conference poster, symposium External use e.g. marketing material, communication, education	High (needs research ethics approval)

Investigator Initiated Studies

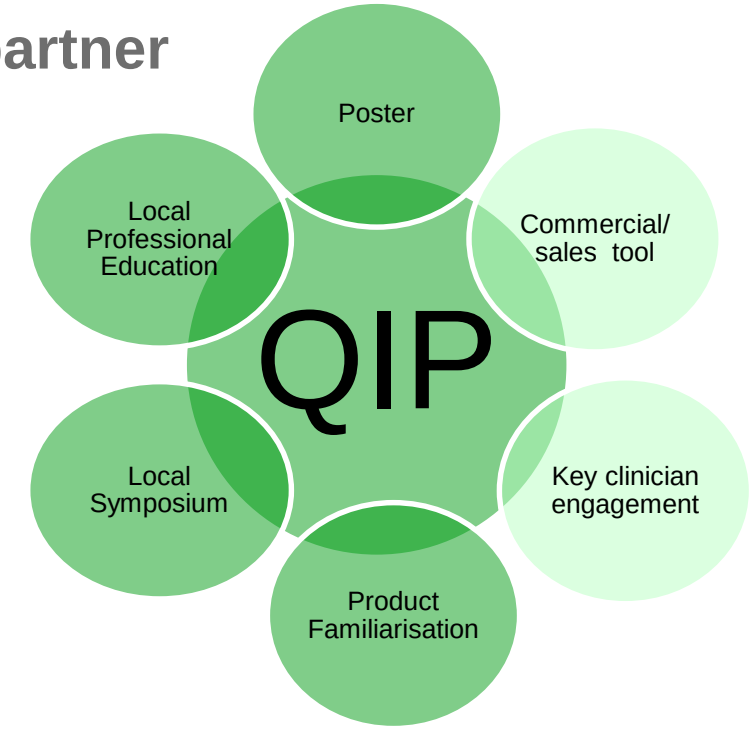
- Clinical trials proposed upon the initiative of clinical Sponsor-Investigators and without the company taking the role as a sponsor

- **NOTE:** Notified bodies might refuse the data from an investigator-sponsored study if it was not conducted in strict compliance with the international clinical investigations standard, ISO 14155.

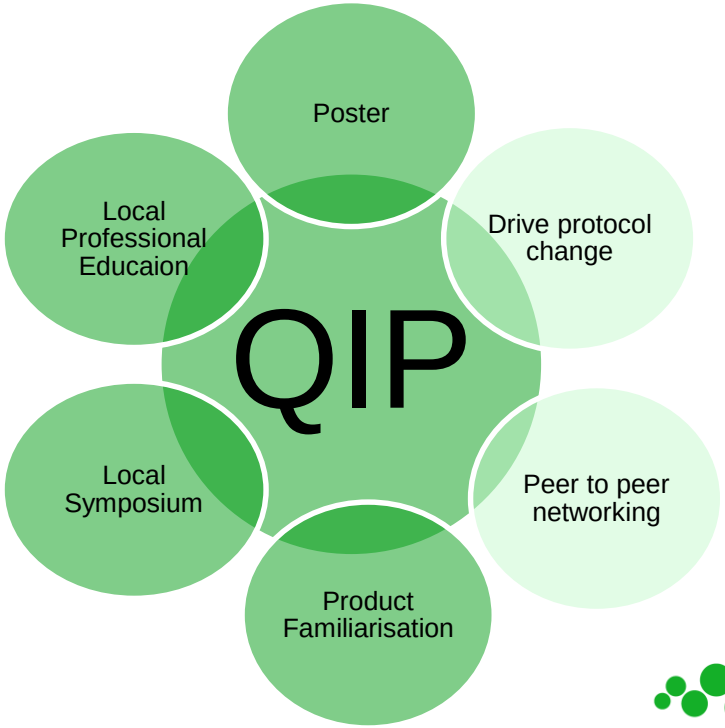
Quality Improvement Programme

A systematic change of a process which results in an improvement for the patient, provider or payor

Industry partner



Clinician



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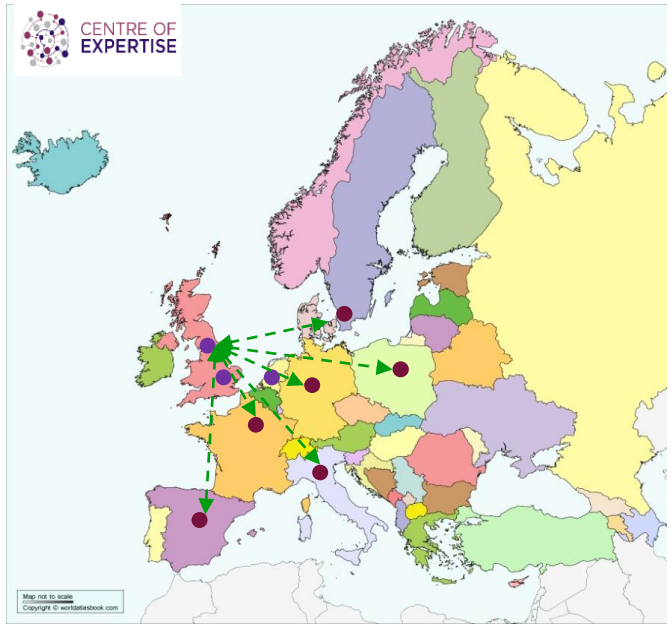
What form can the collaboration take?

- Product donations
- Funding
- Resource provisions: statistics, medical writing

Level of collaboration



Recurring and established collaborations

Fellowships

Research Nurse

One-off individual Studies

My experiences

- Management of over 25 IIS's
  - Yes they are investigated initiated but a close relationship with the investigator and site is key
  - Beware of over-stepping the line in terms of any control by industry partner
  - If there are concerns, over-communicate. Just because a study doesn't meet its endpoints doesn't mean the company wants to bury it!

- Three established COEs
  - Choose your partner wisely
  - Clinician has to champion industry partner throughout the process
  - Slow and painful to set up; short term pain for long term gain

- Leadership of QIP programme
  - Start small and build
  - Molnlycke built an entire new business which grew from a QIP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