Systematic Support for Medical Information (MI): "If it ain't broke, don't fix it"?

What leads companies to consider changing how they support MI?

Good question.

After all, change usually involves both cost and disruption – not least the hassle of negotiating internal processes and issues.

You're also probably busier than you've ever been before, there are always other priorities, and you're expected to do more with less.

Shouldn't the old maxim of "if it ain't broke, don't fix it" apply when it comes to how you're supporting MI?

Key "trigger" events:

- Launching new products
- Extending existing products
- Opening new affiliates
- Acquisitions, mergers, restructuring
- A new CEO
- MHRA inspections

Up to a point, "yes, right!" and, certainly, unless there's a compelling reason to change, backed-up with a solid business case – as well as a strategy for how to handle the internal situation – any effort to change here almost certainly won't get very far.

However, what our customers over the last 18+ years have experienced is that this "yes, right!" is only "up to a point". This is because of key "trigger" events that they've found will cause a significant shift in either or both of:

- The volume of medical information enquiries
- The nature and complexity of medical information enquiries

At that point, the resulting step-change will often push the existing approach initially to its limits, and then beyond them. Typical examples of such "trigger" events include:

- Launching a new product - particularly if it's your company's first or second one
- Extending existing products into new therapeutic areas or marketing them for new indications
- Opening new affiliates
- Acquiring a new company, merging with another company, or internal restructuring
- The appointment of a new CEO or a change in internally-supported technologies
- An upcoming MHRA inspection or, worse, the findings from the last one

"Whilst it's certainly possible to rapidly course-correct... we've found that forward-looking companies are increasingly looking to prepare and plan in advance..."

Whilst it's certainly possible to rapidly course-correct in response to such step-changes – our current "record" for an end-to-end system implementation is 6 weeks – we've found that forward-looking companies are increasingly looking to prepare and plan in advance. This way, they're not trying to figure-out what to do whilst then also in full-on "fire-fighting" mode.

Might some of the above "trigger" events apply to your company, either now or in the future? If so, do you know how you would deal with them? And, in particular, do you know how your existing approach would hold-up?

The Status Quo

For many smaller companies, in particular, the existing approach to MI looks something like this:

- If enquiry handling isn't fully outsourced, enquiries are likely logged on paper (perhaps with a spreadsheet to additionally record some administrative management information)
- If there's a computerised system in place of any kind, it is likely home-made (and likely written in Microsoft Access)
- If there's more than one country with MI staff, chances are that each country does its own thing
- If they exist at all, reference materials (such as FAQs and standard answers) are at best kept on a shared network drive and, at worst, stored across individuals' machines. Staff know what to use and what not to, but:
  - Version control is fairly informal
  - Knowing when something is due for review and/or update isn't automatic
  - Formatting and consistency also varies between documents
- Responses sent to enquirers are distributed between "Sent" e-mail folders and hard copies in filing cabinets
- Although the situation is probably manageable, searching is likely not that easy
- Audits are hardly fun, but they pass without any major findings

This has worked fine to date: it might not be perfect... there are certainly things that would be different "in an ideal world"... there might even be some slightly cumbersome workarounds that you and your colleagues could very much live without...

...but there aren't any immediately gaping holes… and even though wanting to pursue best practice means that a change to the status quo would be a "nice to have" – and maybe even a "should have" – it probably won't happen.

And so you carry on as you have been doing. And everything seems fine (just about). But that's where the "trigger" events we mentioned earlier come in.

When "Nice to Have" Can Change to "Must Have"

It may be that you already know that no such "trigger" events are ever going to affect your company – in which case, that's great, truly! Enjoy the stability!

Equally, it may be that you already find yourself in the thick of the challenges that such "trigger" events bring, in which case:

- You'll certainly have a pressing and urgent business case...
- …but you'll equally likely be wishing that you'd prepared in advance, because the present combination of increased busyness and internal change management really isn't a happy one, to say the least (!)...

"Might now be a good time to start actively considering how you're going to handle that change, rather than waiting until it's upon you?"

Most likely, though, significant change is somewhere in the future. Maybe it's directly anticipated; maybe it's only a possibility at this stage. But, in either case, might now be a good time to start actively considering how you're going to handle that change, rather than waiting until it's upon you?

Might it not be better to know that you've mapped-out the potential "stress" points within MI and that you have a strategy in place for handling them? Whilst they vary with each company, and you'll know better than us which might apply for you, how would you handle the following, for example:

- Tracking Adverse Events and performing reconciliation with Pharmacovigilance, whilst minimising the margin of error
- Searching for and locating past enquiries, together with efficiently reusing existing material and resources
- Scaling to accommodate more users and the ways in which they need to work
- Working alongside any outsourcer partners to maintain an overview
- Sharing information across departmental and geographic boundaries – perhaps even with affiliates in other countries
- Maintaining consistency of answers:
  - Avoiding saying different things at different times
  - Preventing time being wasted through people producing fresh answers to questions they are unaware of colleagues having previously answered
  - "Mitigating against knowledge remaining largely buried in people's heads
- Producing metrics or identifying trends – whether that's to gain a picture of what's going on within the MI team itself, or when working alongside colleagues in other areas: marketing, sales, etc
- Developing and enhancing the role and importance of the MI team for both its internal and external customers
- Meeting the increased expectations of ever-more informed enquirers
- Making sure you can address compliance and audit questions on all these points

Chances are you're already experiencing some of those now; do you know what additional challenges they'd pose if rapid change were thrown into the mix?

Timing is everything, of course – start looking at this too soon, and the need won't be so obvious, and the organisation will (rightly) also have other priorities; start looking at this too late, though, and you'll have missed a real opportunity to plan well for the future.

Are you in the "sweet" spot – aware of the potential need, and with the luxury of being able to plan ahead for it? If so, the good news is not only will you be able to put together a good business case, but you may also find that – organisationally – you'll never experience a better stage of growth in which to make powerful change…

> "Are you in the "sweet" spot – aware of the potential need, and with the luxury of being able to plan ahead for it?"

…but more on that another time…!

In the meantime, if you have a need to better understand your requirements, and/or to put together a sound business case, then do get in touch (www.nipltd.com/contact-us), as we have a growing set of resources aimed at helping with these challenges.

NIP has been developing and supplying its MedInfoSys® solutions (medical information enquiry management systems) to pharmaceutical companies of all sizes for over 18 years – see www.nipltd.com/solutions/pharms/medinfosys*. Offered primarily on a Software as a Service (SaaS) basis (see* http://en.wikipedia.org/wiki/SaaS*), MedInfoSys® is a pure web-based system, optimised for rapid implementations that take control problems away, provide a foundation for management perspectives and expand to accommodate future growth and change.*

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