



Are we nearly there? Resource planning—step by step

by Stephen de Looze

*It is not certain that everything is uncertain.
Blaise Pascal, Pensées, 1670*

The good old days?

When I started my professional career as a medical writer in a large pharmaceutical company nearly twenty-five years ago, resource planning was unheard of in the clinical research department. Projects came along, people were allocated to them, deadlines were written down, and then everyone muddled along as best they could. In most cases, keeping to deadlines was not remotely possible, but this seemed to have little consequence other than some hand-wringing here and there. The inherent uncertainty of clinical research, of the many confounding factors that could lead to alterations in ‘the best laid schemes of mice and men’ (in the immortal words of Robert Burns), and the absence of any real pressure from without were considered just part of the way things were.

The best laid schemes of mice and men

To further confound the situation as far as medical writing was concerned, the whole area was something of a free-for-all: there were no document standards or templates, no defined processes or boundaries as to where medical writing began and ended, and not even a clear idea of which skills would contribute to document development and writing.

One of my jobs in those early days was to write up the minutes of a quarterly departmental meeting where all projects were discussed. Although that involved the rather onerous task of chasing up countless details of projects I barely understood, I quickly realised that this afforded me a unique insight into what was in the pipeline and was potentially coming my way. Before long, I was being asked to take on new staff and build the medical writing function within the company. This is when things began to get interesting.

As soon as word got around that there were folks who actually enjoyed the business of preparing documents, and weren’t that bad at it either, the floodgates opened. Project leaders began calling me daily to ask for support in writing their clinical study protocols and reports, publications and investigator brochures. Sure enough, the day came when I was asked to rewrite an entire clinical submission dossier that had flopped badly at the German health authority, and deadlines became rather more serious.

With my knowledge of what was in the pipeline, and a developing sense of how long projects could take, I realised that, at least in theory, I could attempt to calculate just how many new writers I should be hiring to meet the rising demand for our services. By now it was the late 1980s and our first PCs had arrived, still considered by many to be just glorified typewriters.

One day I discovered how to use a spreadsheet, and how I could just update some numbers and the whole thing would recalculate itself instantly. This was a revelation indeed, and opened my eyes to the power of the PC. I set to work in my spare time, linking scores of spreadsheets, producing some fancy graphics and what I thought was irrefutable proof of the need for a quantum leap in the medical writing staff numbers. I was a writer, after all, and knew the power of documents. Ignoring the advice of an older and wiser colleague, who said that higher management would not believe what didn’t suit them, I sent my thesis to the appropriate senior manager with a request for half a dozen new writers—and sure enough, the response was, “Don’t you have anything better to do with your time?”

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How times have changed!

From these inauspicious beginnings (and the careful reader will realise that I was not to be defeated so easily), the approach that I had developed was taken on by other departments as the pace and pressure stepped up in the industry. My group did indeed grow rapidly to a dozen or more staff. Since then, over the years, I have been able to refine and extend my calculations, gather and share experience with others, and try out different tools to manage the task. (I’ll return to this last point later.)

When our department was spun off six years ago to form our present company, a clinical research organisation, the calculations acquired a vastly greater significance, because they enabled a cost estimate for the client to be made for any given assignment. And yet in its essence, my approach today is little changed from that of twenty years ago, and I will share the key elements with you now.

Step 1: Define the scope of each assignment

For example, when a client requests ‘write a clinical study report’, does this mean just the text body and any in-text, word-processed tables? Does it include the patient safety

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narratives? Literature searching? What about assembling the appendices? Quality control? Electronic publishing? And how many review cycles, each requiring a revised document? Will you receive consolidated comments from reviewers, or will you have to resolve disagreements between them? Is a mock report to be written and separately reviewed? Is there a template and style guide to follow? These and similar questions apply to every sort of medical writing project and will differ from organisation to organisation, or from client to client. In many scenarios, the medical writer is often (sometimes explicitly, sometimes merely by default) a project manager too, and this must also be factored in. So you must establish a sort of ‘baseline’ or standard scope, perhaps standard ‘sub-projects’ (such as patient safety narrative writing or appendix assembly) and then you can make adjustments if the particular job differs from that.

Step 2: Define the skills needed for each project

Is it regular medical writing or senior medical writing or a mixture of both? If your organisation has more than two grades of medical writer, do the job descriptions give a guide as to what the contribution of each grade will be to any given project?

What about contributions of medical writing support staff such as technical editors and e-publishers, if you have them?

I am assuming that the planning of the contributions of other disciplines, such as bio-statistics and data management, will be dealt with else-

Sometimes it is just as well to check

where—but sometimes it is just as well to check. You may also have different medical writing needs if you are, say, developing a clinical study protocol with in-house physicians and statisticians, or if you are joining a fully staffed client team, or working as a writer-cum-project-manager with a bunch of different service providers.

Step 3: Define the complexity of the project

This is by far the biggest challenge, sometimes based only on a few sketchy details, and occasionally little more than crystal ball gazing. And yet it must be done.

The number of documents that take a given amount of time can be graphed approximately as follows (Figure 1):



Figure 1: Number of documents that take a given amount of time

The scale of the x-axis will depend very much on the type of document: it may be from, say, 2 to 100 working days for clinical study reports, or, say, from 50 to 500 working days for submission dossiers. Yes, I have seen a simple abbreviated clinical study report based on a ‘twin’ report generated in two days by search and replace of a key parameter and entering a few new numbers. By contrast, reports on ‘megatrials’, with their extensive analyses and multiple subgroups, may take considerably more than 100 days.

That being said, the only point on this curve which is certain is the origin (x=0, y=0)—in other words, no document uses no resources! Otherwise the curve carries the fairly obvious message that a few documents may be quite ‘quick’, the majority will fall somewhere on a broad continuum, and there will be a few super-complex documents to round things off at the high end.

The important thing to note here is that we are considering *resource time* (per skill) and not *calendar time*, as we would be doing in project planning. This is not just because ‘working days’ (or ‘working hours’) need adjusting for ‘calendar days’ because of weekends and public holidays (though freelance medical writers may make no distinction on this point!). More importantly, if a particular project is to take 50 medical writer working days, it could theoretically be achieved by two medical writers in half the calendar time if they could work entirely in parallel. By contrast, when parts of the project fall outside medical writing—such as review time at the client—this must be added into the overall project timing but does not necessarily affect the resources needed. We’ll talk later about the limits of staffing and ‘telescoping’ project timelines by adding resources, and why I italicised the word ‘if’ above.

For resource planning purposes, you would probably agree that such a continuum is not much help, especially if the details that are supplied are incomplete. We need to be able to categorise projects if we are to come up with a first estimate of complexity. In general, three categories will be sufficient: let’s call them ‘low’, ‘medium’ and ‘high’ complexity projects. However, even before we take this step, we must never forget that this simplification is exactly that—a simplification.

The real world still remains a smeary continuum, and what we are now doing is to pick out three arbitrary points on the curve shown in Figure 1. Even if we allow a little uncertainty in our categories, as shown in Figure 2, this is still a simplification of reality. Nevertheless, it does give some sort of framework to our planning.

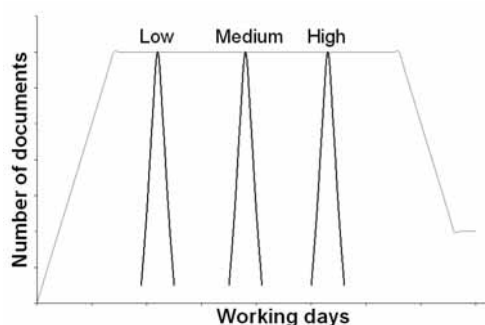


Figure 2: Categorisation into ‘low’, ‘medium’ and ‘high’ complexity assignments



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The next challenge is to define what ‘low’, ‘medium’ and ‘high’ mean for any given project, in the light of the scope that you have defined in step 1, and the skill you have defined in step 2. To avoid a mere tautology (where ‘low’ is just defined as ‘low’), the complexity should be pegged to some measurable ‘variable’. An example for clinical study reports is given by Sam Hamilton in her article ‘Effective Scheduling of Clinical Study Reports’ in this issue. For resource planning purposes, the scheme she describes as a ‘rough guide’ can be refined. For example, if the overall project contains several reports that will all be very similar (this might be the case for a set of studies with the same design and analysis plan but a different comparator drug or different dosage), the first report of the series might be, say, medium or high complexity, and the follow-on reports may (again, for simplicity’s sake) drop down one level of complexity, to low or medium, as the case may be.

Similar considerations apply to any sort of medical writing project. For a clinical submission dossier, the relevant variables might be the overall number of studies, whether the dossier is for a full, new submission or a variation, whether it includes subgroup analyses or a particularly complex integrated safety summary. For an investigator brochure, the number of new clinical and non-clinical studies to be summarised, or a pre-existing document that needs updating rather than writing from scratch (or whether you were the author of the earlier version!) may be relevant.

It is not my aim here to provide you with hard and fast rules that span the whole complexity of all medical writing assignments, and still less to provide you with ‘magic numbers’ that you can put into your calculation as a ‘quick fix’. These will be much influenced by the scope you define for any project, by constraints imposed by your working environment, and by the skills and staff available. This includes such things as whether you have to follow complex style guides or standard operating procedures, whether you have a slow staff turnover and few ‘interface’ issues, whether you often have new staff training-on-the-job, or whether you are dealing with nearby or distant departments, subcontractors or clients. Nevertheless, I hope these considerations give you an idea of how to begin to dissect this complex issue of complexity and arrive at numbers that suit your own situation.

Over the years, I have noticed that some projects, such as clinical study reports or investigator brochures, can be relatively tame animals, provided (and this is a big proviso) your team has a fair idea of how the final document should turn out. There may be a reasonable template or other documents to serve as models. Danger lurks even here, how-

ever, in uncertainties inherent but often not apparent in the process: review cycles are a particular source of grief, but technical steps such as document assembly processes, or electronic specifications (especially if these change mid-way) can bring unexpected additional complexity. In the case of study results, unwelcome or ambiguous findings at the last minute can also set the cat amongst the pigeons, which in practice means increasing the number of review and re-writing cycles and hence increasing the complexity and resource needs.

By contrast, some projects seem by their very nature to be wild beasts, most notably writing clinical protocols, or other planning documents. In these cases, the production of draft documents often will trigger new ideas, or whole re-planning cycles, sometimes starting from scratch. Frequently it would be a more sensible use of resources if the medical writer were not brought onto the project until ideas are fairly well advanced, but many teams, once having been provided with the service, are unwilling to manage without the luxury of letting the medical writer iron out the wrinkles and reveal the issues needing re-discussion. This is good news for medical writers searching for interesting work, of course, but it introduces a lot of uncertainty into the planning.

A signal to recruit new staff or to expand your reservoir of freelancers, or—perish the thought!—turn away business

Your best friend is your experience and instinct, and your ability to balance taking a certain amount of risk (if you are providing a cost calculation to a client, you may lose the project if you assume a worst-case scenario) with some built-in safety net if the goalposts move. You must also be in a position to keep a close eye on things as the project unfolds. The more details you know about a project, the more you can pinpoint its location on the real-life curve in Figure 1—whether ‘lower than low’, ‘higher than high’, or at some intermediate point between categories.

Step 4: Determine long-term and short-term availability of each resource

If you are managing a pool of resources, you need to know how much of each skill is available at any given time. If your long-term planning reveals a chronic shortfall, it should be a signal to recruit new staff members or to expand your reservoir of freelancer subcontractors, or—perish the thought!—turn away business.

So the first step is to calculate the baseline or yearly availability of your resources to projects. For a full-time staff member, this will be:

[Total number of working days per year] minus [paid leave] minus [sick leave] minus [non-project related time].

I’m not aiming to provide hard and fast rules that span the whole complexity of all medical writing assignments

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The total number of working days per year is of course the number of weekdays minus public holidays. This should be straightforward, but a few things need to be considered. Public holidays vary from country to country and in some countries from region to region as well. In some countries, public holidays falling on a weekend will be replaced, in other countries (such as Germany), it's hard luck. For a baseline value, the average number of total working days per year should be estimated—I find that 20 days per month or 240 days per year is as good an estimate as anything else in my own working environment. For part-time staff, everything has to be adjusted accordingly.

The paid leave will obviously vary from company to company but should be easy to determine. Check the records in your company's personnel department to get a reliable average figure for the number of days lost to sick leave. Non-project related time includes everything from the number of days training you provide (EMWA conferences and other training events), to the time your staff spend reading background material, studying company SOPs, and maintaining their personal training folders, to all non-project related meetings and social events. It includes the time you allow your senior staff to spend training the junior staff. You'll be surprised how much non-project time comes out of this calculation.

These times will reduce the theoretical 20 days/month availability quite considerably—in my experience, 15 days/month (180 days/year) baseline availability for projects is the most realistic average estimate for medical writers: but this will vary from country to country, from company to company and from skill to skill.

However, when you are planning short term, different considerations apply. Months do vary in their total number of working days. Christmas

**Christmas
never goes away**

never goes away. Your staff member may not have holiday planned in that month (or you may have the authority to cancel holiday). Alternatively, they may have the whole month away. In a particular month, no training may be scheduled, and after surreptitious scrutiny of your employees during regular meetings, you may reasonably assume that no days will be lost to illness! So in the short term, you might in some circumstances assume 100% availability (i.e. 20 days), which is markedly different from 15 days. You may even have more than 100% availability from a dedicated worker who is prepared to put in substantial overtime in the short term to meet project timelines. But then you have to remember that this particular resource will need to be correspondingly under-planned in the months ahead.

You may have come across an entirely different approach to quantifying resources that is sometimes used. This is to think of resources in terms of 'full time equivalents' (FTEs) and fractions or multiples thereof. This approach

may work best for projects which require dedicated staff over long periods—study coordinators, for example, working over several years on a single project. In all my experience, the FTE approach simply does not work for medical writing projects, which are most commonly of short duration and are characterised by frequent changes in the assumptions needed for planning, and by the requirement for flexibility of staffing in the short term. The FTE approach also masks the difference between short-term and long-term availability and can lead to serious mistakes in the planning calculations.

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Step 5: Allocate resources to projects

If, like me, you are a manager of a medical writing function, your most important task is to allocate your staff to projects so that they are not chronically over-planned

or under-planned, both of which lead to frustration and job dissatisfaction—and underperformance or worse. I would go as far as to say that this is the most important management skill you should develop. It is essential to remember that your staff are not just numbers on some resource planning sheet but each are at their own stage in their professional development, have their particular knowledge, strengths and interests, and 'learning curve'. If you are building medical writing teams on large projects, then you will also take into consideration which of your staff best complement each other and how you can bring newer or less experienced colleagues up to speed by working alongside more senior colleagues.

For this human side of resource planning, there is no substitute for your own well-developed skills as a manager, your knowledge of your staff through regular meetings, assessments and training programmes, and your ability to step in and support them when the need arises. But alongside the human factor, software tools are indispensable to enable you to establish some sort of framework to optimise your staff's projected workload. They also tremendously ease the burden of re-assessing plans and work schedules as project scope and timelines shift and change.

Over two decades, I have used several tools, from my first simple spreadsheets to customised and complex project management software, to off-the-shelf products such as Microsoft Project. I now firmly believe that a simple spreadsheet is the best help. This is because a spreadsheet is something that you can devise and customise to your own needs, that you can instantly access and update, and most importantly, you can make available on a shared server to

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your staff who can review and adjust their planning themselves. After all, your staff are closest to the project details, can implement planning shifts as soon as they emerge, and work best when empowered to manage their own time within the framework that you have established.

The more complex, company-wide tools I have had to use in the past often required data entry by a dedicated project management department and involved handovers at each stage, whether the entry of new specifications, or checking the information has been understood and handled correctly, or the distribution of the outputs generated by the software. The scope for ‘disconnects’ was consequently large and, in the case of rapidly shifting project requirements (often on crucial deliverables such as submission documents on tight timelines), these complex tools and processes had too much lag time to be useful in my day-to-day work.

A simple spreadsheet also has the great advantage that the entry of numbers in columns gives a strong visual element to the resource spread, as well as the all-important quantitative information as to how many days (or hours) are required over a pre-determined time span. With a basic knowledge of spreadsheet functionality, you can easily sort the numbers and subtotal them by project, by type of activity or document, and most usefully, by staff member.

The spreadsheet I use is little more complex than the example shown in Figure 3, which is an excerpt for the skill medical writer (MW), identified here by the person’s initials.

Project code	Activity	MW	Sept 08	Oct 08	Nov 08	Dec 08
XYZ123	CSR	DS		5	10	10
XYZ456	IB	RA	10	5		2
XYZ789	CSP	RA	5	5	5	
XYZ532	CSP Amend	DS	5			
XYZ999	CTD 2.5, 2.7	LL	20	20	20	
XYZ999	CTD 2.5, 2.7	PJ	20	15	10	
ABC456	CSR Tables	WV	2	2	2	2
ABC987	CSR	WV	15	15	5	5
ZZZ321	CSR	DS		15	5	5

Figure 3: Overall resource plan (excerpt)

The number of columns assigned to the months ahead is flexible, though I find that almost all plans will be accommodated within a 12- to 15-month forecast. Projects that are further off into the future can be listed without defined resource allocation by month or medical writer, but with a comment on the likely resource need. More columns can be used to capture essential additional information (such as contact names, drug indication or notes on the uncertainty in the planning). At any one time, my ‘master’ spreadsheet

will contain a few dozen rows. A printout of the spreadsheet with filtered data subtalled for each staff member serves as a basis for our routine discussions on the overall planned workload and the status of the projects.

I also add a row for planned holiday or training for each staff member, so that this is included in the total planned time in any given month. It is precisely the flexibility that makes this tool so well suited to my needs.

As an added bonus, at the end of the year, I archive a copy of the spreadsheet to serve as a ‘snapshot’ record of what sort of documents we have worked on during the year—information sometimes requested by prospective clients. The ‘master’ spreadsheet itself has a constantly roaming window on the future, shifting forwards as the months roll by. It remains a planning tool: we do not retrospectively capture the time actually used on past projects on this spreadsheet but have other systems better suited for recording that.

The limitations of planning

So finally, with Figure 3, we have arrived at ‘The Resource Plan’. The spread of resources over time also reflects detailed project planning knowledge, such as timing of crucial deliverables from other departments or your client (protocol outlines, analysis plans, programmed tables, draft package inserts, or whatever), planned review cycles and other steps. The first thing I check at each update is the subtotal per staff member, and whether this matches their baseline availability. My underlying assumption is that the plan will never be

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nearer to within 15% of real life. So if a staff member is theoretically available 20 days per month, I am happy if their monthly planned work is between 17 and 23 days. The inexactness of project plans means that the chances are high that a couple of days planned in one month will actually be used in the preceding or following month. If there is, however, chronic short-term over-planning—23 days per month over more than three months, for example—then this gives me a signal to monitor the project more closely and start thinking about corrective measures such as negotiating longer timelines, adding resources to the project, or re-assessing the resource requirement more critically. Or maybe I know that the staff member will be able to take on a higher workload in the short term. Analogous considerations apply to chronic under-planning. The further off a project is, the more relaxed I can be about deviations from real life.

Sometimes I plan projects half a year or more away with more marked over- or under-planning. This is partly because I may need to give the project a ‘home’ with the underlying assumption (in the case of over-planning) that the assigned staff member will be the lead writer, but that we will find a support writer or a contractor nearer the time if the planning remains critical. This can be captured in a

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comment on the spreadsheet. But I also live with uncertainty because experience has taught me that the planning of far-off projects often changes: for example, it may be possible for the assigned writer to begin the project earlier, or the deadline may shift backwards because a study runs longer than the planned schedule. These changes have the effect of stretching out the estimated resources over more time and bringing the required resource per month to a realistic level even if the overall resource need remains the same. In addition, the actual resource need may be better defined nearer to the start of the project when more details have become apparent. By then planned staff allocation may have to change anyway because of unforeseen clashes with other projects that have drifted out of scope in the meantime.

A job that can be done by a medical writer in 25 days cannot be done by 25 in one day!

I mentioned earlier that you should never forget that resources are real people and not numbers on a spreadsheet. A job that can be done by a medical writer in 25 days cannot be done by 25 medical writers in one day! Even though this seems like a statement of the blindingly obvious, I deal almost daily with requests that imply something along these lines, often when projects have spiralled out of control and people are desperate to meet deadlines. On large projects, it may be possible or indeed necessary to assign several writers to work on pieces in parallel. This may be desirable even on smaller but critically important projects, where the unplanned absence of a writer due to illness or some other event, or a sudden shift in resource need, may endanger the deadlines. I regularly assign more than one writer to clinical submission dossiers, for example, even if the work appears theoretically achievable by one person in the timeframe. This reduces stress all round and provides a safety net if the planning changes. However, additional communication and project management time must be added into the overall resource time allocated to the project if several people are working on different pieces of a project. Of course the writers may then work on other (ideally less critical) projects in parallel to fill out their individual resource plans.

Don't take out a mortgage on your future worries

A crucial understanding is that planning is a tool: it is a means to an end and should not become an end in itself. You should only devote a limited amount of time to drawing up plans for a far-off project that are likely to change even before the project begins, if it begins at all. In the words of my grandmother, "Don't take out a mortgage on your future worries". I have encountered people in project management departments who did nothing else except produce vastly detailed project plans extending over dozens of pages with thousands of items, and whose working days

were completely filled with tracking all the changes to the planning even before anything had begun. This is a looking-glass world and should remain where it belongs: in the realm of the fairy story, delightfully captured almost one hundred and forty years ago by Lewis Carroll:



The most curious part of the thing was, that the trees and the other things round them never changed their places at all: however fast they went, they never seemed to pass anything. "I wonder if all the things move along with us?" thought poor puzzled Alice. And the Queen seemed to guess her thoughts, for she cried, "Faster! Don't try to talk!" Not that Alice had any idea of doing THAT. She felt as if she would never be able to talk again, she was getting so much out of breath: and still the Queen cried "Faster! Faster" and dragged her along. "Are we nearly there?" Alice managed to pant out at last. "Nearly there" the Queen repeated. "Why, we passed it ten minutes ago!"

Lewis Carroll, *Through the Looking Glass* (1871).

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Illustration:

Alice and the Red Queen from an original Illustration by Sir John Tenniel for Lewis Carroll's *Alice's Adventures in Wonderland and Through the Looking Glass*; JM Dent & Sons 1954, 1970: 139.