

CHAPTER 2

Developing a publication plan for a multicentre study

Ideally, publication plans should be developed at the earliest stages of trial planning. Thinking about potential publications as you design the protocol can increase your chances of producing publishable results. Early planning and clear communication can also prevent later problems with authorship.

For large, multicentre studies, it is unfeasible for all investigators to be named as authors on publications. It is therefore helpful to agree **authorship** criteria at the start of the study. This will avoid many problems caused by unrealistic **expectations** or misunderstandings. At the outset, it may not be possible to predict exactly who will qualify as authors, but it is usually possible to agree how authorship will be allotted. The protocol development team (which usually comprises clinicians or senior scientists from the sponsor, a statistician and three or four key investigators) is a good starting point for a **writing group**, but, in the course of the study, personnel may change, so you cannot necessarily predict the exact composition of the final group, nor exactly who will qualify as authors.

Ground rules for invitation on to a writing team might be:

- protocol development team plus one investigator from each centre (to be nominated by each centre), or
- principal investigator, statistician, plus top recruiting investigator from each country, or
- principal investigator, five top recruiting investigators, plus company employees who meet ICMJE criteria.

Authors' responsibilities should be discussed and agreed at the outset. An invitation to join a writing team should not be viewed as an automatic qualification for authorship. Authors must expect to contribute to data interpretation and developing the publication.

Ground rules for authorship should be clearly communicated to everybody involved with the study, so that disagreements can be resolved promptly, and everybody has the same expectations.

Some companies and, to a lesser extent, academic institutions have their own authorship policies. These may be helpful (you should certainly be aware of them) but, if you consider the policy contravenes journal authorship criteria, such as the **International Committee of Medical Journal Editors (ICMJE)** criteria, you should be prepared to challenge them.

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Authorship policies that may fall foul of accepted criteria include:

- never permitting employees to be named as authors on papers relating to company products
- only permitting a set number of employees to be named as authors (e.g. one per paper)
- always requiring an employee or particular individual (e.g. head of department, or professor) to be included as an author.

Such policies are likely to create problems of **ghost** or **guest authors**. It is much better to agree ground rules for each study.

Thinking about publications can also help to focus the study design. Imagining how the results might appear in a journal may help to identify weaknesses and omissions. Involving patients or carers in clinical trial design is good practice, and may also help to identify interesting publications or increase the scope of potential publications, e.g. by including a quality of life assessment.

Publication strategies (and especially plans for authorship) should be clearly set out and communicated, preferably in writing within the **investigators' agreement**.

Identifying target meetings can help to plan study timing – although this inevitably involves some crystal ball gazing, so you should not expect to be too precise. However, aiming to submit an abstract by a certain deadline may help to focus minds. If you wait to create your strategy until the data are ready, you might find you have needlessly missed a crucial deadline by a few days. Thinking about likely publications may also help to develop the **data analysis plan**, e.g. by identifying sub-group analyses at the outset.

An example of an outline publication strategy at the start of a study is shown in Table 2.1.

Table 2.1: Outline publication strategy prepared at the start of a study

<i>Publication</i>	<i>Topic</i>	<i>Meeting/ Journal</i>	<i>Target audience</i>	<i>Submission deadline/ target</i>	<i>Publication date</i>
Abstract 1	Efficacy data	ESMO	Oncologists	May 06	Nov. 06
Abstract 2	Safety data	ESMO	Oncologists	May 06	Nov. 06
Abstract 3	Sub-group data (haem)	EHA	Haematologists	Jan. 07	June 07
Abstract 4	Quality of life	<i>Cancer Nursing</i>	Oncology nurses	Feb. 07	Aug. 07
Main paper	Main results	Oncology (? <i>JCO</i>)	Oncologists	Q3 06	Q1 07
Paper 2	Sub-group analyses	Haematology (? <i>Blood</i>)	Haematologists	Q1 07	Q3 07
Paper 3	Long-term follow-up	Oncology	Oncologists	2008	?

(Q = quarter; thus Q3 06 indicates the third quarter of 2006)

Once the results are available, the plan can be refined. At this stage, you should identify the authors, **key messages** and target meeting/journal for each publication. An example is given in Table 2.2.

Table 2.2: More detailed plan prepared when results are available

<i>Publication</i>	<i>Key message</i>	<i>Authors</i>	<i>Meeting/ Journal</i>
Abstract 1	Tumorzap increases survival in cancer patients	X, Y, Z	ESMO
Abstract 2	Tumorzap causes less nausea than Chemowiz	Y, Z, X	ESMO
Abstract 3	Tumorzap induces complete remission in some haematological malignancies	Z, X, H	EHA
Abstract 4	Tumorzap improves patient quality of life	X, Y, Q	Cancer Nursing
Main paper (P1)	Tumorzap increases survival and is well tolerated in patients with advanced cancer	X, Y, H, Q, Z	JCO
Paper 2	Tumorzap induces complete remission in some haematological malignancies	Z, X, H	Blood
Paper 3	Long-term (two-year) follow-up confirms survival benefit with Tumorzap	Y, X, Z	Ann Onc

You should also produce a detailed timetable and circulate it to everybody who will be involved with the publication. Agreeing a timetable is particularly crucial if you have tight deadlines to meet. It also helps by setting out the steps to publication. These vary, depending on the complexity of the publication (which will affect how many drafts and review rounds you might need) and the study sponsor/organisers (who will have different requirements for review and approval).

If several people, or several organisations, are involved in developing a publication, a detailed plan can also be helpful in identifying who is responsible for each action or stage. A possible plan is shown in Table 2.3.

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Table 2.3: Detailed publication plan showing timelines and responsibilities

<i>Publication</i>	<i>Data ready</i>	<i>1st draft</i>	<i>Writing group review</i>	<i>Collate comments write 2nd draft</i>	<i>Xth draft ...</i>	<i>Internal company review</i>	<i>All authors final review</i>	<i>Submit</i>	<i>Decision expected</i>	<i>Publication expected</i>	<i>Current status</i>
A1	5 April (Stats)	15 April AW	30 April	5 May AW	...	10 May SM	12 May	15 May PA	July	30 Oct. 06	Submitted
P1	5 April (Stats)	5 May AW	26 May	10 June AW	...	1 July SM	10 July	17 July CA	mid-Sept.	Jan. 07	Drafted

Key: AW = a writer; SM = senior medic; PA = presenting author; CA = **corresponding author**