



(Friday) 15 December 2000

**Memorandum**

To: Center faculty, staff, and friends

Fr: Curt Meinert

Re: Memos for trialists concerning presentation and publication of primary results and mainline papers from trials

**Definitions** (fr Meinert; *Clinical Trials Dictionary*)

**ancillary publication** *n* - [research] 1. A **publication** containing original **ancillary results**.  
2. A publication bearing on an ancillary **aim** or **objective** of a specific **research project**; in the case of **trials**, usually publications devoted exclusively to results from **ancillary studies**. rt: **primary publication, secondary publication**

**mainline paper** *n* - [trials] A **paper** detailing the **design, methods, or baseline results** of a **trial** or containing original **results** related to the primary **objective** of a trial and written by study personnel commissioned by the **investigative group** or their representative. syn: **primary publication** rt: **secondary paper**

**primary publication** *n* - [research] 1. A **publication** containing **original data**, especially one containing a **primary result**. 2. A publication from a **study** or *investigation* considered essential in relation to the primary **purpose** or **objective** of a specific **research project**; in the case of **trials**, includes publications of primary results and on the **design, methods, and baseline results** of the trial. syn: **mainline paper** rt: **secondary publication, ancillary publication**

**primary result** *n* - [research] A **result** (defn 3) of direct relevance to the primary **objective** of a **study**. In **clinical trials**, a result based on the **primary outcome measure** or on the **design variable** of the trial. rt: **secondary result, ancillary result**

**secondary paper** *n* - [trials] A **paper** dealing with a secondary **objective** and written by study personnel commissioned by the **investigative group** or their representative. syn: **secondary publication** rt: **mainline paper**

The series of memos to follow (first of which attached) are prompted by discussions regarding policy on publication of results in trials. Having worked with dozens of groups in "birthing" multicenter trials, I know, sooner or later, that groups have to come to grips with questions concerning when and what to present and publish.

This series of memos is predicated on the belief that:

1. Investigators assume a moral obligation to publish when they undertake a trial
2. Investigators should not undertake a trial if they lack the right of primacy
3. Results should be published in peer-reviewed, MEDLINE indexed, journals
4. Datasets from trials should be made available to the public when papers are published or when the trial is finished
5. Results should not be presented prior to publication (*publish first, present later*)
6. Results in multicenter trials should be published under the corporate form of authorship
7. Titles for primary manuscripts should include the study name and the term *trial* or *randomized trial*
8. Papers should include credits and acknowledgments