| Roche's Basis for Reluctance or Refusal to Share Data | Response |
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| "Unfortunately we are unable to send you the data requested as a similar meta analysis is currently commencing with which there are concerns your request may conflict. We have been approached by an independent expert influenza group and as part of their meta analysis we have provided access to Roche's study reports." (Oct. 8, 2009) | It is unclear why another group of independent researchers would prevent Roche from sharing the same data with our group. |
| Cochrane reviewers were "unwilling to enter into the [confidentiality] agreement with Roche." (Dec. 8, 2009) | The terms of Roche's proposed contract were unacceptable to us. We declined to sign for two reasons: 1) all data disclosed under the contract were to be regarded as confidential; and 2) signing the contract would also require us "not to disclose … the existence and terms of this Agreement". We judged that the requirement to keep all data, and the confidentiality agreement itself, secret would interfere with our explicit aim of openly and transparently systematically reviewing the trial data and accounting for their provenance. |
| Roche says that it was "under the impression that you [Cochrane] were also satisfied with its provision based on our correspondence earlier this year (March 2010)." (June 1, 2010) | We did not immediately realize that what Roche had provided was incomplete. Irrespective of whether we had at one point seemed "satisfied," Roche had not delivered what it publicly promised in the *BMJ* on Dec. 8, 2009: "full study reports will also be made available on a password-protected site within the coming days to physicians and scientists undertaking legitimate analyses." |
| "… around 3,200 pages of information have already been provided by Roche for review by your group and the scientific community." (Aug. 20, 2010) | What is important is completeness, and 3,200 pages is a fraction of the full study reports for the ten Kaiser trials Roche promised to make available. |
| "Roche undertook this action [release of 3,200 pages] to demonstrate our complete confidence in the data and our commitment to transparency to the degree to which patient confidentiality, data exclusivity and the protection of intellectual property allow." (Aug. 20, 2010) | This implies that release of the promised-but-never-released data would impinge on "patient confidentiality, data exclusivity and the protection of intellectual property". This does not seem to apply to many elements of clinical study reports (e.g., the trial protocol and reporting analysis plan), and it is unclear why personal data could not be anonymized. |
| "The amount of data already made accessible to the scientific community through our actions extends beyond what is generally provided to any third party in the absence of a confidentiality agreement." (Aug. 20, 2010) | It is irrelevant what is "generally provided". What is relevant is what was promised and the need for public disclosure of clinical study reports. |
| "Over the last few months, we have witnessed a number of developments which raise concerns that certain members of Cochrane Group involved with the review of the neuraminidase inhibitors are unlikely to approach the review with the independence that is both necessary and justified. Amongst others, this includes incorrect statements concerning Roche/Tamiflu made during a recent official enquiry into the response to last year's pandemic by a member of this Cochrane Review Group. Roche intends to follow up separately to clarify this issue. We also note with concern that certain investigators, who the Cochrane Group is proposing will carry out the planned review, have previously published articles covering Tamiflu which we believe lack the appropriate scientific rigor and objectivity." (Aug. 20, 2010) | Despite Roche's promise and our request for specifics, Roche never responded directly. |
| "We noted in our correspondence to the BMJ in December of last year our concern that the first requests for data to assist in your review did not come from the Cochrane Group, but from the media apparently trying to obtain data following discussions with the Cochrane Review Group. This raised serious questions regarding the motivation for the review from the outset. We note that in subsequent correspondence regarding your next planned review you have copied a number of journalists when responding to emails sent by Roche staff." (Aug. 20, 2010) | Our view is that Tamiflu is a global public health drug and the media have a legitimate reason for helping independent reviewers obtain data, which includes being informed of our efforts to do so. |
| Cochrane reviewers have been provided with "all the trial data [they] require …" (Jan. 14, 2011) | We disagree. First, it is up to us to decide what we require. Second, we now know that what was provided was not enough. For example, Roche did not provide us with the trial protocols and full amendment history. |
| "You have all the detail you need to undertake a review and so we have decided not to supply any more detailed information. We do not believe the requested detail to be necessary for the purposes of a review of neuraminidase inhibitors." (April 26, 2011) | We have still not received what was promised in December 2009, and we know that what we have received is deficient. |
| "It is the role of Global Regulatory Authorities to review detailed information of medicines when assessing benefit/risk. This has occurred, and continues to occur with Tamiflu, as with all other medicines, through regular license updates." (April 26, 2011) | Independent researchers such as the Cochrane Collaboration share the goal of assessing benefit/risk, and require all details necessary to competently perform this function. |
| "Roche has made full clinical study data available to health authorities around the world for their review as part of the licensing process." [42] (Jan. 20, 2012) | Roche may have made full clinical study data "available" but that does not mean they "provided" all regulators with full clinical study data. For at least 15 Tamiflu trials, Roche did not provide the European regulator (EMA) with full study reports, apparently because EMA did not expressly request the complete clinical study reports. (Correspondence with EMA, May 24 and Jul. 20, 2011) |

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