



European Medicines Agency  
Pre-authorisation Evaluation of Medicines for Human Use

London, 8 June 2007  
Doc. Ref: EMEA/177203/2007

**EMA Workshop on the  
Guideline for first-in-man clinical trials for potential high-risk medicinal products**

**Tuesday 12 June 2007, 9.00-17.30, (Room 2A)**

**AGENDA**

| Chairperson of the Workshop: Eric Abadie |                                                                                                                                                                                                                                                                      |                                                                                                                                                                                         |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 08:30                                    | Registration                                                                                                                                                                                                                                                         |                                                                                                                                                                                         |
| 09:00                                    | Welcome                                                                                                                                                                                                                                                              | Patrick Le Courtois (EMA)<br>Eric Abadie (CHMP)                                                                                                                                         |
| 09:15                                    | Background information <ul style="list-style-type: none"><li>The TGN 1412 case</li></ul>                                                                                                                                                                             | <a href="#">Ganesh Suntharalingam &amp; Nicki Panoskaltsis</a>                                                                                                                          |
| 09:40                                    | Overview of the draft guideline                                                                                                                                                                                                                                      | <a href="#">Jan Willem van der Laan</a>                                                                                                                                                 |
| 10:00                                    | Specific aspects <ul style="list-style-type: none"><li>How to define high risk medicinal products</li><li>Relevance of animal models</li><li>Calculation of MABEL and 1<sup>st</sup> dose in human</li></ul>                                                         | <a href="#">Christian Schneider</a><br><a href="#">Beatriz Silva-Lima</a><br><a href="#">Jenny Sims</a>                                                                                 |
| 10:30                                    | Coffee break                                                                                                                                                                                                                                                         |                                                                                                                                                                                         |
| 10:45                                    | Specific aspects (continued) <ul style="list-style-type: none"><li>Elements of design of FIM clinical trials</li><li>Commission guideline on clinical trials applications</li><li>GCP impact</li></ul>                                                               | <a href="#">Ian Hudson</a><br><a href="#">Brian Davis</a><br><a href="#">Pierre-Henri Bertoye</a>                                                                                       |
| 11:15                                    | Comments on the draft guideline <ul style="list-style-type: none"><li>EFPIA</li><li>EUCROF</li><li>EuropaBio</li></ul>                                                                                                                                               | <a href="#">Tim Hammond</a> & Solange Rohou<br><a href="#">Antoine Cournot</a><br><a href="#">Christiane Abouzeid</a>                                                                   |
| 11:45                                    | Overview of written comments followed by plenary discussion                                                                                                                                                                                                          | <a href="#">Jean-Marc Vidal (EMA)</a>                                                                                                                                                   |
| 12:45                                    | Lunch                                                                                                                                                                                                                                                                |                                                                                                                                                                                         |
| 14:00                                    | Breakout sessions <ul style="list-style-type: none"><li>A - Quality aspects</li><li>B - Identifying risk factors</li><li>C - Transition from preclinical to clinical</li><li>D - Dose escalation and monitoring</li><li>E - Planning of the Clinical Trial</li></ul> | Martijn van der Plas / Glenda Silvester<br>Christian Schneider / Marc Pallardy<br>Beatriz Silva-Lima / David Jones<br>Ian Hudson / Bertrand Diquet<br>Martyn Ward / Brigitta Pettersson |
| 15:15                                    | Coffee break                                                                                                                                                                                                                                                         |                                                                                                                                                                                         |
| 15:30                                    | Plenary discussion <ul style="list-style-type: none"><li>Report from each subgroup</li></ul>                                                                                                                                                                         | Panel: Beatriz Silva-Lima, Jan Willem van der Laan & experts<br>Rapporteurs                                                                                                             |
| 17:30                                    | Concluding remarks                                                                                                                                                                                                                                                   | Eric Abadie                                                                                                                                                                             |