Items identified in Work-Group meetings during ICORD 2007
WG II, WG III & IV, and WG V

WG II: Product Discovery and Development: Linking the Academic Research Community to the Pharmaceutical and Biotechnology Industries

Subject areas for WG II ICORD 2008

1. Databases and resources session (workshop theme)
2. Educational sessions
    a. VC-session
    b. "Resources for academics" session – grants, trail design,)
    c. SME-session
3. Additional planning for ICORD 2008
    a. Partnering event?
    b. Poster session and mingle?

WG III: Development of Rare Diseases Research and Orphan Products Development Assessment Tools: Possibilities Restrictions, and Solutions
WG IV: Recruiting Patients for Clinical Research Studies and the Value of International Collaboration

1. Improved Information Sharing/Enhanced Links ("Orphanet Plus")
2. This would consist of a website that in addition to containing original material, would have links (internationally) to
    a) various tools, including materials, gene banks, data sets, animal models and other basic research
    b) active protocols and study registries
    c) active research networks
    d) sources of patients who might be interested in participating in studies
    e) standard diagnostic criteria for conditions/diseases

3. It was also recommended that articles and/or letters be sent to major journals and the lay press publicizing the website.

4. Education regarding efficiencies and improvements in clinical trials on aspects such as:
    a) study design
    b) data analysis (including interim analysis procedures and data monitoring) [data monitoring would include the point raised by Jan-Inge regarding sequential study design]
    c) interpretation (including role of p-values)
    d) study outcome selection
    e) need for long-term follow-up and adverse event assessment.

Those needing education include investigators, sponsors, and regulators.

WG V: Genetic Testing for Rare Diseases in International Settings

1. EuroGentest and GeneTests should continue to develop a collaboration that would allow maximum visibility of European and US laboratories offering clinical testing.

2. Some clinical laboratories have constraints on the number of samples that they can process; thus, it is important to remember that a laboratory that is the sole source of clinical testing may not be able to manage the volume of tests requested if its services are marketed globally. In other words, just because one or two laboratories are identified as providing a clinical test, does not mean that all those who seek such testing will be able to actually get the test.

3. Standard mutation nomenclature should be used for descriibing any mutation identified in a database. Further discussion of this would be a good topic for the May 2008 meeting in Washington DC. One suggestion is to have staff from the National Center for Biotechnology Information (NCBI) of the NIH participate in such a discussion.