



THE SCIENCE *of* POSSIBILITY



**US Informal MedDRA
User Group Meeting**

Cambridge, MA

Hot Topic Panel

Ian Slack | October 28, 2011

Hot Topic Panel

- Eric Tate (Allergan **Pharma**)
- Pat Revelle (**MSSO**)
- Henry Chen (Thesis inc. **CRO**)
- Patricia Sorn (Oracle **Vendor**)
- Dr. Steve Goldman (Stephen A. Goldman Consulting Services **Consultant**)



Hot Topics

- Certified MedDRA Coder (CMC) experiences of the group so far. Has this credential been of value in your role?
- Future of the US Informal MedDRA User Group – use of Yahoo Groups, globalization, CRO and Vendor involvement.
- CMQ's – Development and implementation.
- Medical Device coding.
- What are the credentials of the coding signoff personnel at other companies? Is an MD or Pharm D necessary? What about RN?
- What metrics are used for forecasting? Do you use metrics for performance management?
- For small companies that outsource all coding (CDM and Safety) to multiple CROs, what are the best tools to ensure consistent coding across CROs within the same program?
- A mechanism for sharing coding related job postings within the MedDRA user group?
- Does anyone have a global synonym list attached to both safety and clinical jobs? If so, how large is it and how do you manage conflicts or coding that does not agree with guidelines?
- Should MedDRA contain a medical definition for each PT? This may be very helpful for coders to reference as well as biostatisticians, medical writers, clinicians and others who are involved with review and analysis of data. Would the MSSO consider creating a working group to develop the strategy and foundation to build these definitions?



Thank You!

