Interactions with Regulatory Authorities

Medical University of Vienna

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The Medical University of Vienna is…

- a medical research and education facility with a tradition spanning over almost 650 years
- Europe‘s largest school of medicine with almost 8,000 enrolled students located in close vicinity to Europe‘s largest hospital (Vienna General Hospital), whose 1,500 physicians it sources

Key data

- 30 clinical departments and clinical institutes
  - 62 Outpatient departments, 351 Specialized outpatient departments
  - 106.869 inpatient cases
  - 539.611 outpatient cases
  - 53.174 surgeries
- 12 medical theoretical centres and departments
- Total federal funds: 385 Mio EUR/year
- External funds: 82.7 Mio EUR
- 5,500 total employees (incl. 3,600 scientific staff)

Clinical Trials at the Medical University of Vienna

- About 1200 clinical trials and epidemiological studies per year
- 150-200 drug trials per year
- >100 trials on medicinal products
- Close interaction with industry
- Focus on early stages of clinical development (FIM)
- Clinical Trial Unit
- Statistical Consulting
- Largest Ethics Committee in Austria

Challenges & hurdles for academic clinical studies

Feedback from quick survey conducted for this workshop:

- Recently regulatory framework was tailored to big pharma research
- Databases (e.g. final Eudract report) are not appropriate for many academic and early phase studies, e.g., PK studies.
- Mandatory upload of final report for early phase studies generates enormous administrative work and has little benefit.
- No technical solution available for posting information in EudraCT result database of studies which have not recruited and were stopped before inclusion of first participant.
- No efficient system for the reporting of SUSARS & helpdesk response slow
- Competent authorities started to challenge/judge content of research (previously only ethics committees did this) and opinions often differ between countries
- Fees for academic studies (regulatory approval of studies, costs of EMA SA)
- Funding and support of academic clinical trials (National and EU Grants do not cover the full costs of clinical trials)

Training

- No training provided by Austrian regulatory agency
- No regular update provided about administrative news or requirements
- Some trainings available from universities

Experiences on dealing with regulatory authorities

- Very good interaction with AGES, constructive and short response times
- Individual members of the university are/were members in EMA committees and working parties.
- University members involved in 500 scientific advise procedures for EMA.
- Passive SA from AGES fast.
- Objective settings and standards for GCP inspections to be improved.
- Good collaboration with EMA in regulatory methodological research (Joint publications, workshops, …)
- To ensure a higher level of involvement of academic experts in EMA activities more incentives needed.

Thanks.