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OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

The Risk Management Plan and the first Marketing Authorisation Application - a practical approach

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Background

- New MAA for late stage oncology indication (Orphan drug designation [ODD])
  - In combination with chemotherapy followed by maintenance monotherapy
- Company clinical programme had been stopped
  - primary endpoints not met
- Investigator Sponsored Study (ISS) showed efficacy in an indication that was not originally part of clinical development programme
- Decision made to submit MAA
  - Using ISS as the single pivotal study
  - plus other studies in the company development programme
  - pre-submission scientific discussion with EMA

Project related challenges

- Non-company sponsored study, therefore
  - No control over study design
  - No control over time and composition of data collected
    - Time to onset was recorded as being at the next clinic visit
    - Outcome was not collected for non-serious AEs
- Resource limited
  - Competition with other company MAAs (higher priority) for resource/senior stakeholder review
  - Conflicting priorities – only 1 full FTE in safety department dedicated to the submission, others had other priorities to manage

Project related challenges

- Final decision to submit MAA not confirmed
- But - tight project timelines which kept changing
- Staff motivation
  - Working on a submission with no confirmed decision to submit
- Lack of company foresight and planning
  - Due to inexperience
  - Timing and sequence of higher level document draft/review/approval
  - Review would be considerable based on volume of data

Safety related challenges

- Establishing the safety profile and presentation of safety data was complex
  - Large amount of clinical data >5,000 patients
  - Data not in the indication sought but from studies in other solid tumours
  - Varying study designs
- Lack of planning and foresight
- Constantly changing priorities/timelines
- Shifting of goal posts

Safety related challenges

- Establishing identified and potential risks
  - Based on ISS or on company clinical programme?
  - Different patient populations
- Risk profile very similar to those of other drugs in class
  - But large % of patients required dose modifications (dose reductions and dose pauses) and ultimately discontinued treatment due to toxicity
- Two particular toxicities (non life-threatening) resulted in the most dose modifications
- Reduction of discontinuations to increase benefit/risk

Overcoming project challenges

- Non-company sponsored study
  - Need to validate ISS data
  - Understand data and what is possible and realistic / scientifically credible
  - Explain data capture and missing data early at pre-submission meeting and in HLDs as appropriate
- Resources
  - Almost always a problem so need to work smartly
  - Being specific in requirements and precise in execution
  - Utilise staff/consultants with previous MAA submission experience (where available)
  - Careful planning and reactive to changes

Overcoming project challenges

- Project timelines
  - Being adaptive and responsive
  - Communication and education – sequence of documents –some dependent on prior approval of others
  - Negotiation – some final text in the RMP dependant on other modules in the submission – agreement from senior stakeholders that final text in RMP would be added at the approval stage
  - Manage expectations of team and stakeholders

Overcoming safety related challenges

- Complex and high volume of data
  - Working smartly
  - Creative application of scientific principles
  - Presentation of ISS data
  - Pool comprising of ISS study and other MAH sponsored combination studies
  - Pool comprising MAH sponsored monotherapy studies
  - Applying observations across the programme bearing in mind what was applicable to the indication being submitted
  - Extensive literature review to try and characterise identified and potential risks due to limitations of ISS study
- Identification of Identified and potential risks
  - Initially based on data from pre-clinical programme
  - Added to by what was observed in ISS study and across the MAH development programme.
  - Finally looking at other class effects - identified as IIRs and IPRs
  - Decision to include in RMP

Overcoming safety related challenges

- Decision whether to include additional risk minimisation measures (aRMMs) or not
- Risk management to date
  - Mostly well managed by investigator education and communication in protocols and in proposed SmPC
  - Similar approach for post-marketing
- Preparing possible aRMMs/scenarios/possibilities
  - Benefit to patient
  - Acceptable to EMA
  - Achievable/cost effective and measurable

Lessons learned - Suggestions

- Always follow the science
- Early planning
- Stay focused
- Communication
- Transparency
- Pragmatism
- Creativeness
- Reactivity/Flexibility
- Resourceful

Questions

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We welcome you all to our future conferences of OMICS International

5th International Conference & Exhibition on Pharmacovigilance & Clinical Trials

On

September 19 - 21, 2016 at Vienna, **Austria**

http://pharmacovigilance.pharmaceuticalconferences.com/