The role of a Chief Medical Officer

UK BioIndustry Association

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View from Investors – what they want from a CMO

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View from Investors – what they want from a CMO

Dr Hamish Cameron, Operating Partner, SV Health Investors
CMO Summit, March 5th 2018

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HEALTH INVESTORS

The CMO as part of the investment thesis

- People – science – plan – investment
- Context of a private VC backed biotech
- CMOs as part of a founding team – full/part-time
- Discovery interface
- Level of experience, knowledge, skills and track record of achievement
- Medical lead – gateway to the challenges of translation and the interactions with KOLs, clinical Ad Boards – developing the very best medical thinking
- Likely to be “new” science and “early” stage development
- Absence of infrastructure - responsible for all the medical research/medical affairs functions although many components outsourced or delivered by consultants
- A broader context – across discovery/regulatory/clinical/commercial/business/market access leading to an “exit”

Special challenges for the biotech CMO

- Communication and influencing
- Effective regulatory interactions
- New science and treatment modalities
- Working across different indications
- Interacting with CEOs and CSOs
- Rare diseases – interactions with parents, patients, associations, media…..
- Creating ideas for risk mitigation and developing options
- Fundraising input – CMO a key focus for new investors joining a syndicate
- Business development – “selling” the story
- Working as a full member of the biotech company C-suite team

View from a regulatory perspective – what they need from a CMO

Dr David Jefferys
Eisai

A view on the current and future role of the Chief Medical Officer from the Regulatory /Regulators Perspective

Dr David Jefferys
Senior Vice President Global Regulatory and Patient Safety Eisai
Board Member of the FPM
5th March 2018



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human health care

Current role

Short survey

- Do all companies have a CMO?
- SMEs vs mid/large Pharma
- Global vs Regional vs National
- Relationship with the CSO (Chief Scientific Officer) and Rand D Departments.
- Role in product development
- Role in patient safety pre and post marketing:

  Relationship with EU QPPV
- Role in medical information and market access
- Role in patient access, named patient use patient access programmes
- Role in ethical issues, data transparency.
- Trusted spokesperson/role in crisis management
- Contact person with stakeholders/key opinion leaders

- Statutory role:

  EU level, Member State level
- Expert reports
- Expert signatory
- MD and IVD Regulations 2017/745 and 2017/746:

  Concept and role of the "Regulatory

  Expert "

The future

- patient focussed and patient centred drug development
- Increased role in market access /accelerated pathway submissions
- Combined regulatory /HTA evaluations (EU proposal for 2020)
- Expansion of the role of the regulatory /compliance expert
- Brexit implications?

Concluding remarks

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View from the coalface – what is expected

Dr Penny Ward
Karus Therapeutics

View from the Coalface

Dr Penelope Ward MBBS FFPM

CMO, Karus Therapeutics (Achilles Therapeutics, Blue Earth Diagnostics, Topivert Pharma, Glenmark, Novimmune)

How it's been for me…..

Reasons to be grateful:

- Past experience
  - CD (PI-III) in multiple TAs, med affairs, consumer health, PV and med info, multiple geography regulatory interactions, crisis management
- Lifelines
  - Consult the expert
  - Call a friend
  - Ask the audience
- Interminable optimism

What I wish for:

- Financial literacy (as opposed to budget management experience)
- Better understanding of business development
- Better tools
  - costing software (site and CRO), 'e'feasibility for trial designs, 'e' protocols, patient data – genetic, outcomes, pooled datasets (retrospective control trials)
- The ability to remember that 'better' is the enemy of 'good'

View from the Coalface

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Discussion

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