THE EVOLVING MEDICAL AFFAIRS FUNCTION

Helen Kane, MD, PIVOT MSL
We are a specialist consultancy which was borne out of a passion for the MSL and the wider Medical Affairs function:

- **We engage** within the global biopharmaceutical industry as a trusted and respected partner
- **We define** and drive standards of field medical excellence and value
- **We build** in-role capabilities, optimize value and effectiveness
- **We support** the MSL and the MSL Manager throughout their professional development journey
‘To bring life saving & life enhancing medicines to patients’

Achieved through:

- Discovery
- Development
- Regulatory Approval
- Commercialisation

Drug Lifecycle
Improved outcomes for patients

‘Patients all over the world are living longer, healthier and more productive lives, thanks to innovative medicines developed by biopharmaceutical companies.’

DRUG DEVELOPMENT PROCESS

DISCOVERY

PRE-CLINICAL

CLINICAL TRIALS

FDA Review

Manufacturing

PHASE I

PHASE II

PHASE III

PHASE IV

DURATION 10 - 15 years

COST $2.5bn

10,000 - 15,000 Compounds

250 Compounds

5 Compounds

1 FDA approved Drug

0.5 - 2 YEARS

3 - 6 YEARS

6 - 7 YEARS

PRE-IND

IND SUBMITTED

EMA SUBMITTED

20 - 100 volunteers

100 - 500 volunteers

1,000 - 5,000 volunteers

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A bridge between Development and Commercial
THE EVOLVING MEDICAL AFFAIRS FUNCTION

COMMERCIAL ORGANISATION

MEDICAL AFFAIRS

“A support function”

OLD WORLD: Medical marketing & information
THE SHIFTING LANDSCAPE

- Safety concerns
- Patient voice
- Trust in pharma
- Physician access
- Complex science
- Digital healthcare
- Competitive environment
- Cost pressures
- Transparency
- Payer demands
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COMMERCIAL ORGANISATION

MEDICAL AFFAIRS
“A support function”

NEW WORLD

COMMERCIAL ORGANISATION

MEDICAL AFFAIRS
“A crucial partner”
THE NEW WORLD

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PEER TO PEER RELATIONSHIPS

ASPIRATION

A trusted scientific partner

REALITY

- ‘I meet at least 4-5 different people from one company but they don’t seem to talk to each other’
- ‘I have information overload and am time poor’
- Sometimes it takes weeks to get an answer to my questions, I don’t know why. By then I am wrestling with another problem’
ACTIVITIES & INDIVIDUAL ROLES

ENGAGE: Connector
EXCHANGE: Facilitator
EDUCATE: Educator
GENERATE: Collaborator
INFORM: Communicator
CORE COMPETENCIES

- Therapeutic expertise
- Scientific acumen
- Clinical research
- Healthcare systems
- Critical appraisal
- Biostatistics
- Investigator Initiated Trials

- Communication (verbal and written)
- Team working & collaboration
- Presentation
- Networking & influence
- Relationship management
- Emotional intelligence

- Industry awareness
- Corporate understanding
- Strategic planning
- Governance & compliance
- Technology & IT
- Project management
1. Medical Affairs is uniquely placed to engage as a strategic and trusted scientific partner in ultimate support of the patient

2. Trust needs to be earned through credibility, objectivity and an understanding of stakeholder needs

3. Essential competencies have expanded to include scientific knowledge and expertise, business acumen, leadership and communication skills

4. Medical Affairs is in a phase of rapid evolution, organisations need to support and develop their teams so that they can deliver in-role excellence