CDDF MULTI-STAKEHOLDER WORKSHOP

USE OF REAL WORLD DATA TO OPTIMISE ONCOLOGY DRUG DEVELOPMENT AND ACCESS

6-7 July 2016
London, United Kingdom

Closing Chairs' Reflections

Linda McNamara (Roche)

Felipe Fernandez (Novartis)

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State of play with RWD

- Much going in Europe – the 'so what' factor?
- Challenges of data access and harmonisation
- IMI GETREAL – progress there/the efficacy-effectiveness gap/role of patient & physician behaviour
- Role of registry's RWD in development?
- The 'why' and 'why not question'?
- Opportunities – new tools/new end points?/rare diseases when RCT not feasible
- Concerns – over interpretation/"parachute" effect in clinical dossier
- US vs. Europe – sharing of data/learning with the regulator example
- True clinical challenge – transferability of RCTs results into wider population e.g., elderly mCRC population
- Advances in integrated data platforms for research
- Looking to outcomes in RWD – replicability in different settings/role of validation
- We are missing the patients' perspective/ PROs
- Terminology – clinical trials/pivotal trials/RWD etc. etc.

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.....Day 2

- Time frame for methodological research
- Interplay or not of association/causation
- Pivotal trials not the end and be all – the car engine analogy
- Messy records (into CRF) vs. EHR
- Short term follow NOT helpful
- Separation between ‘practice’ and ‘research’
- Marginal gains not BIG BANG analogy!
- Timely data capture and its utility
- How do we address regulators’ concerns
- Simplicity vs. complexity
- Burden of ever increasing evidence generation???
- Patient registry pull through – planned vs actual
- Validation of biomarkers
- Actionable end points for decision making
- Creating synergies with existing initiatives: MAPPS/AP/PAES/PASS

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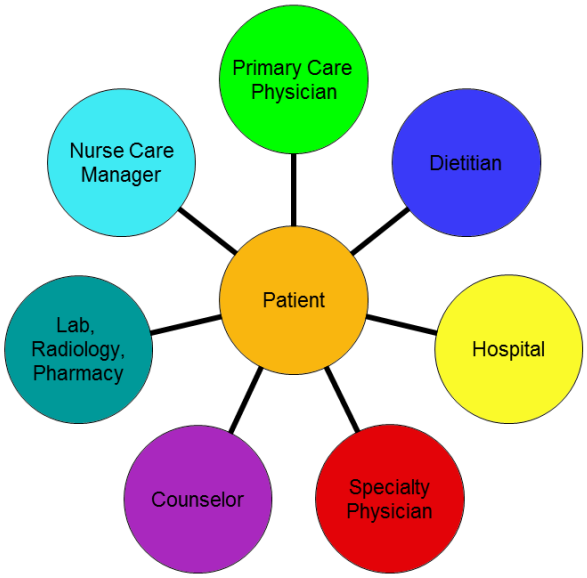
...And

OPPORTUNITIES /OPTIMISIM/ NEW THINKING

CAUTION/ CONCERN



CHALLENGES/ ACCESS/ ROBUSTNESS

RIGOUR/ VALIDATION/ REPLICABILITY

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