Going strong since the Millennium

How H.M. Pharma Consultancy Can Assist With Drug Repurposing

V 3.1 November 2015

Integrated Drug Repositioning Services

- Identify opportunities
- Freedom To Operate checks
- Intellectual property assistance
- Drug development plans
- Identifying and managing CROs
- Regulatory assistance

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Integrated Opportunity & FTO Searches

- Evaluate which sort of therapeutic application gaps your product could actually fill
  - Would physicians prescribe it?
  - Would payers reimburse it?
  - Would patients be compliant?
- Market assessment – always the first filter criterion
  - Current status, trends, and dynamics
  - HMPC has published dozens of therapeutic area and technology assessments
- Assessing potential licensors and external proposals
  - Due diligence: look at the entire data

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Assistance With Intellectual Property

- Designing patent specifications to fit the repurposing niche
  - Different strategies for “on-target” and “off-target”
  - Yet other strategies if the API is already marketed
- Patent writing (the actual body text)
- Outlining what needs to be in the claims
  - Formal claims to be written by the patent attorney
- HMPC has broad experience with this:
  - Patent attorneys and scientists typically have communication problems
  - Supplementing, not replacing, attorneys' work

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Designing The Drug Development Plan (I)

- Has to be considered in integration with regulatory path
  - 505(b)2 at FDA and/or EMA Hybrid Application
  - Or full NDA/MAA, depending on “jump vector”

505(b)(1) vs. 505(b)(2) Drug Development Timeline			
	Discovery	Preclinical Research	Clinical Studies
505(b)(1)	2-5 years	1-3 years	8-15 years
505(b)(2)	<1-3 years	<1-2 years	2-5 years

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Designing The Drug Development Plan (II)

- Laboratory work to assess feasibility
  - Cell-based models (using molecular *in vitro* tests alone can be seriously misleading)
- Preclinical work to support the API's new application
  - Efficacy and safety in animal models
- New formulation design
  - Match the route with the new application
  - For marketed drugs: differentiate against generic competition
- Identify fastest route to enter clinical evaluation

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Coordinating With Contract Research Organizations

- CROs are usually good at connecting with their clients
- However,
  - If several CROs work in parallel, coordination is needed
  - Commissioned work (but not management) should be outsourced
- H.M. Pharma Consultancy has two decades of experience with such matters
- We have good contacts, also to specialist CROs (e.g. in neurology and ophthalmology)

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More Than Just The Final Step: Regulatory Assistance

- Just as patenting, regulatory considerations are an integral part of the entire drug repurposing process
- Anticipate attitude and reaction of authorities
- We can initiate and manage Scientific Advice procedures at the EMA and FDA
- H.M. Pharma Consultancy has approved SME status at the EMA
    - Scientific Advice regulatory fee reduction for non-EU corporate developers

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Advanced Data Management And Communication

- Your data – provided by you or generated for you – are safe with H.M. Pharma Consultancy on all levels
- We run our own private cloud
  - Commercial cloud services are only used where the customer explicitly specifies it
- We can accommodate most secure modes of communication and data exchange
- Redundant and distributed backups are a strict policy

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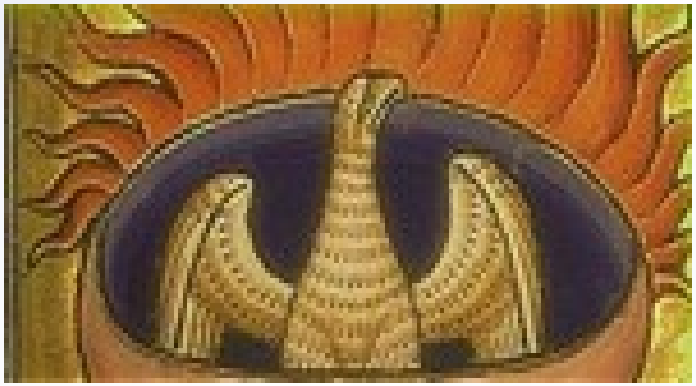
Online & Publishing Activities In Drug Repurposing

- We have founded, and are managing, the discussion group “Drug repurposing - reprofiling – repositioning” on LinkedIn:
  http://www.linkedin.com/groups?gid=3705627



- Our CEO is Repositioning Editor at ASSAY and Drug Development Technologies

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*** THANK YOU FOR YOUR ATTENTION ***

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