

Industry experience of multi-stakeholder early advice consultations

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The following slides represent my personal views on this topic and should not be seen as GSK's position

Outline

- Why industry is interested in multi-stakeholder advice consultations
- Early vs late in the development process
- The GSK pilot with Tapestry
- What we learned and didn't learn
- Ideas for future consultations

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Why Industry is interested in multi-stakeholder advice consultations

- Optimise global development plans to best deliver to different stakeholders
 - Clarity for all parties on the evidence required to demonstrate value
- Make visible and discuss differences between stakeholders data requests, with a view to reducing the development bandwidth
- Share challenges of development and look for improvements

Improve efficiency of drug development process

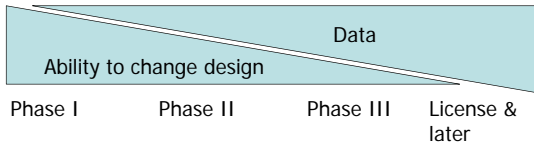
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Selected quotes from participants

- "My optimism relates to the fact I have heard a real willingness to bring the reimbursement and regulatory processes closer together which I think has got to be good for all of us"
- "...creates a so-called win/win situation for everybody"
- "Over the last five or ten years I have heard many people talk about gathering a variety of people like this ...and it had never happened. I am very encouraged to see this happening now"
- "What I have heard today, and already last night, has really sharpened my awareness of the pressures that managers and the pharmaceutical industry feel. I was close to forgetting about that"
- "I have to say I am perhaps a little more optimistic this evening about the possibility of new drugs between Metformin and insulin. I was not so optimistic coming this morning, but I have heard a lot of things and I am now a little more"

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When is too Early vs too Late in the development process?



It depends on:

1. What you want to know
 - i. Patient population, comparator selection, endpoints, statistical analysis, place in therapy, etc.
2. How large are uncertainties for your development plan
 - i. Novelty of drug, investment required, competitive situation, etc

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The GSK pilot with Tapestry

Dec 2010 consultation on GSK novel early-stage type 2 diabetes asset

- Hosted at EMA; joint-chair EMA & HTA
- Participation: EMA, HTA's (Germany, UK, France, Neth, Swe), clinical & patient experts.

Process:

- Submit dossier (target profile, potential indications, comparators and place in treatment paradigm, endpoints, safety & side effects)
- Initial (phone) meeting to clarify & agree questions
- Stakeholders develop answers
- Face to face meeting to discuss openly areas of (dis)agreement
- De-brief by phone (mainly process)

Principles:

- Focus on the methodology, not the outcome, of value assessment
- Collaborative and equal: all participants should submit questions
- Non-binding advice/ no formal minutes
- Sufficient time invested before and during consultation
- Use pilot assets as stepping stone to broader application

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What we learned and didn't learn

Did learn

- Comparator
- Trial population
- Proof of concept study design and supporting data
- Discussion of an early-stage asset is "safe".
- High level of consistency between all stakeholders (sometimes expressed differently).

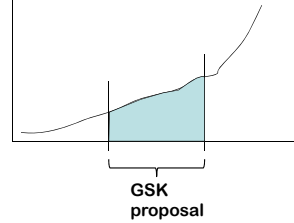
Didn't learn

- Trial population
- End-points (durability of control)
- Expectations for post-launch data generation

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Example of different viewpoints – trial population

Level of marker to select patients



Stakeholder	Lens for discussion
Regulators	Benefit/risk at population level
Value assessors	Cost-effectiveness
Payers	Affordability
Patients and clinicians	Real-world use; excluding patients; benefit/risk at individual level

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