

Risk management

Nuovi processi

Medical Governance

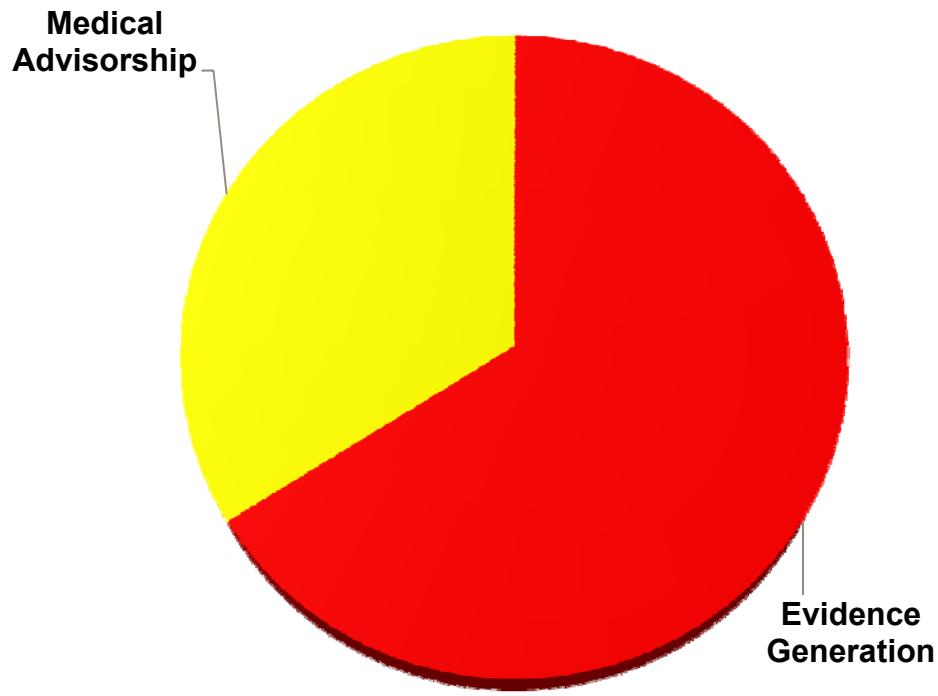


Giuseppe Recchia

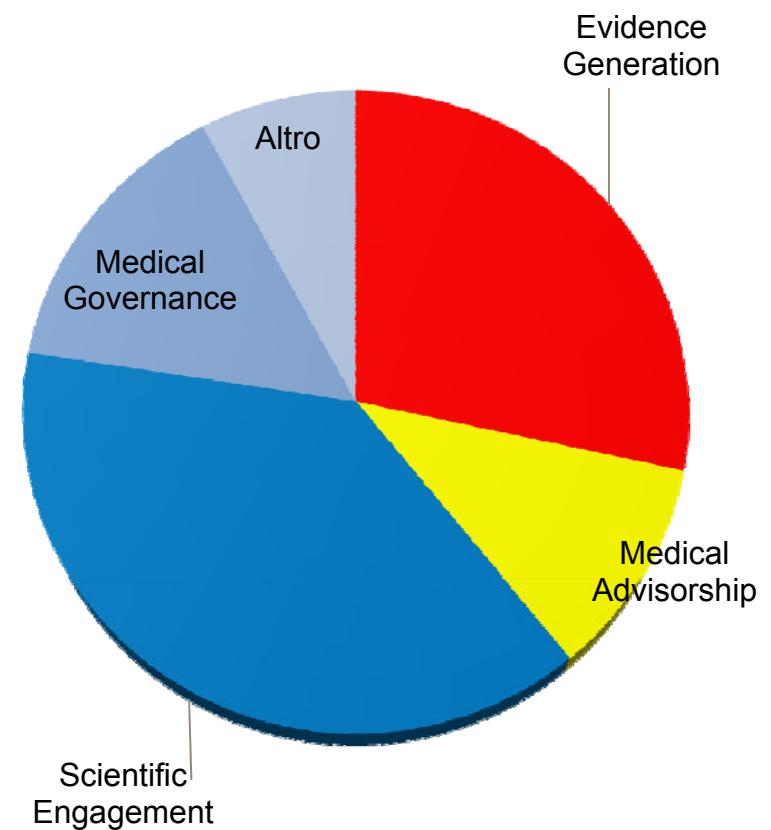
Agenda

1. Introduzione
2. Evoluzione
3. Nuovi Processi
 - a. *Scientific Engagement 2011*
 - b. *Nuovo Modello Commerciale 2016*
 - c. *Patient Engagement 2017*
4. Risk Management
5. Conclusione

Evoluzione Processi Scientifici 1997 - 2017



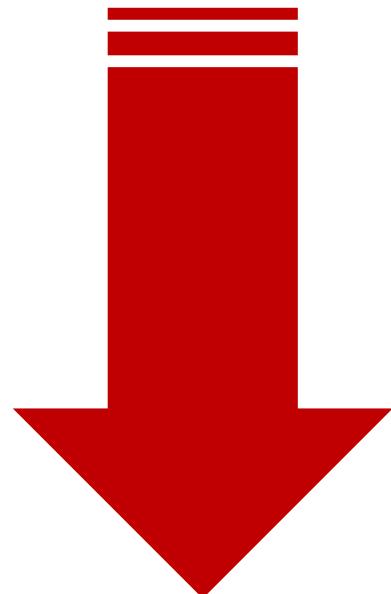
1997



2017

Evoluzione Ambiente - 2010 C.I.A.

Corporate Integrity Agreement

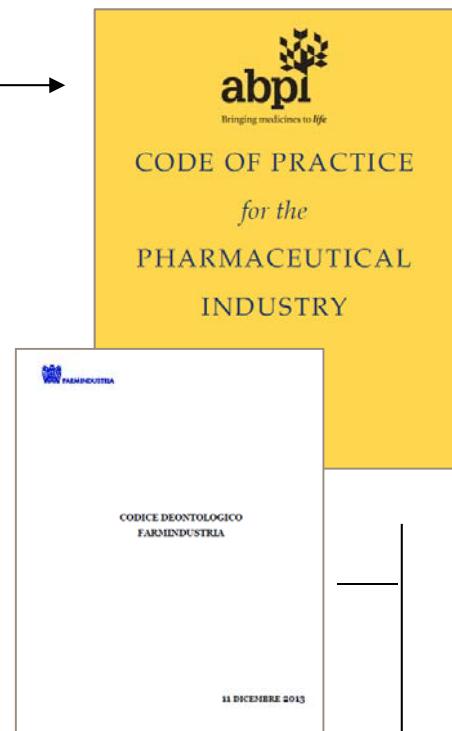


- h. the manner and circumstances under which medical personnel from Medical Affairs (including Regional Scientific Managers (RSMs)) interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

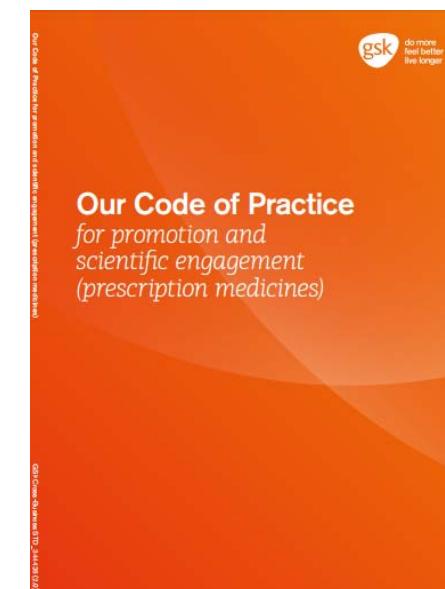
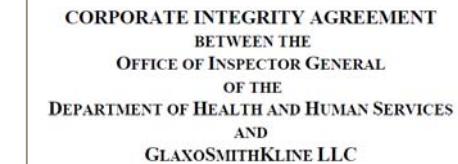
Leggi e Norme



Codici



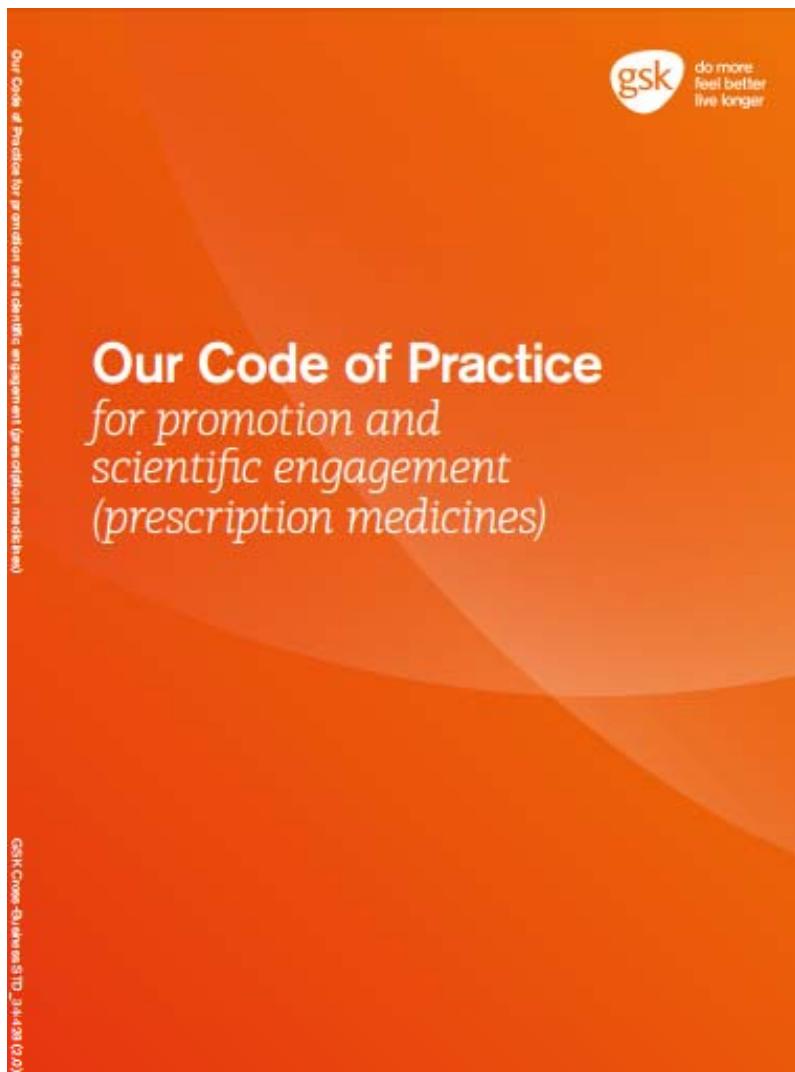
Politiche



Sistema
Organizzativo & Procedurale

2017

Promotion and Scientific Engagement



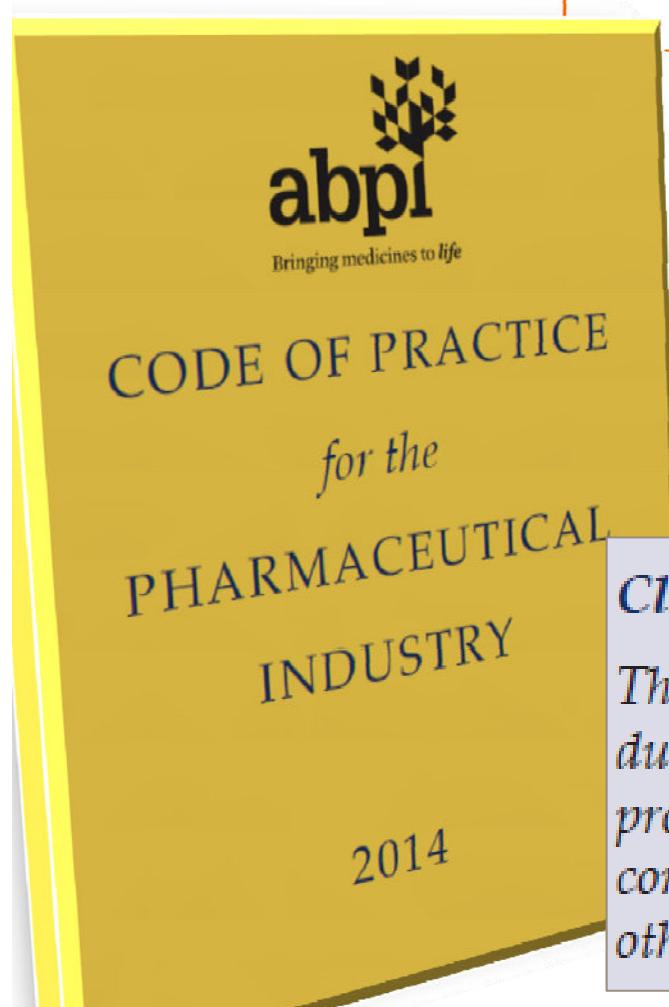
Scientific engagement is the non-promotional interaction and exchange of information between GSK and external communities in order to advance scientific and medical understanding. This includes the appropriate development and use of our medicines, understanding the management of disease, and improving patient care.

The activities and materials associated with scientific engagement are non-promotional in nature and intent, and proportional to the scientific need. There is a clear distinction between scientific engagement and promotional activities.

Scientific engagement activities covered by this code are:

-
- Seeking external advice, insights and information.
 - Scientific communication of our research.
 - Supporting independent medical education.
 - Scientific interactions with payers, governments and public health organisations.

Scientific Engagement



DECRETO LEGISLATIVO 24 aprile 2006, n.219
Attuazione della direttiva 2001/83/CE (e successive direttive di modifica) relativa ad un codice comunitario concernente i medicinali per uso umano, nonché della direttiva 2003/94/CE.

Art. 113

**Titolo VIII
PUBBLICITA'**

rispondere

- **Engagement**
 - ✓ Interaction
 - ✓ Exchange

discutere

Clause 3 Marketing Authorization

The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause.

Scientific Engagement

22 Our Code of Practice for promotion and scientific engagement

2

Scientific engagement (non-promotional)

2.1 Introduction	p24
2.2 Principles for scientific engagement	p25
2.3 Accountability and approval	p27
2.4 Use and selection of vendors	p28
2.5 Seeking external advice, insights and information	p29
2.6 Scientific communication of our research	p33
2.7 Supporting independent medical education	p37
2.8 Scientific interactions with payers, governments and public health organisations	p41



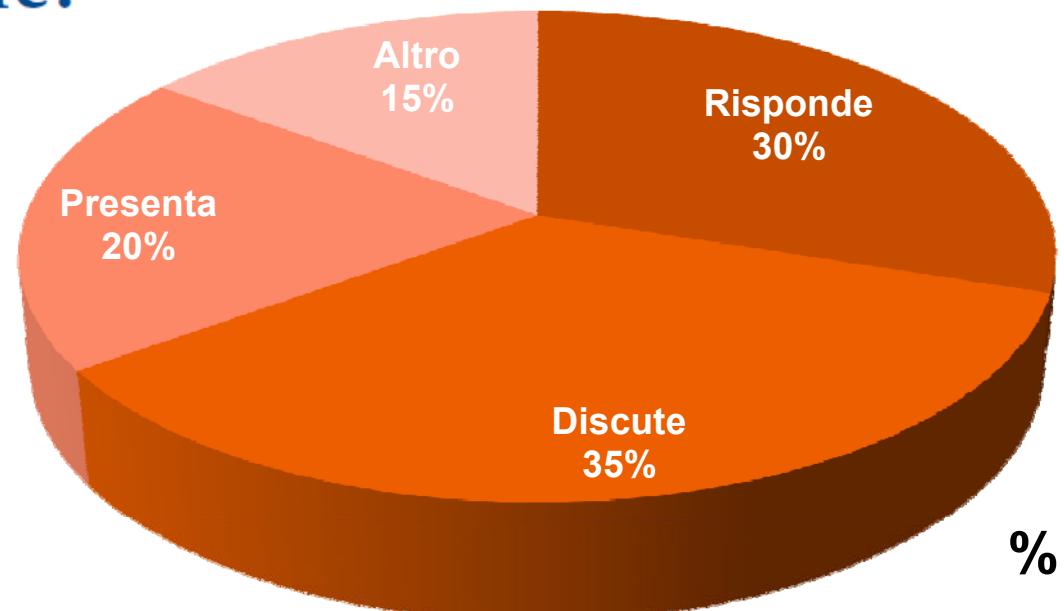
- STD-GSKF-415: Standards for external interactions by Medical and R&D staff
- POL_132175: Policy for use of digital channels
- STD_340448: Standard for interacting with patient organisations
- SOP-GSK-301: Procedure on protecting and mitigating risk from internal and external communication activities
- SOP_297780: US Pharma market research: criteria for designing and executing market research conducted in the US
- SOP_54813: Medical Information responses to healthcare professionals and consumers
- SOP-GSKF-416: Scientific engagement of individual and groups of patient caregivers and consumers to seek advice, insights and information
- SOP_344448: Engaging with Healthcare Professionals (HCPs) to provide services
- POL-GSKF-408: Policy on human subject research
- SOP_53431: Public disclosure of human subject research (Pharma)
- SOP_9000026959: Public disclosure of human subject research (Vaccines)
- POL-GSK-016: Policy on grants and donations
- SOP-GSK-016: Grants and donations SOP
- SOP-GSK-007: Interactions with officials from government and inter governmental agencies

Scientific Engagement

Roberta Bodini, Andrea Rizzi, Giuseppe Recchia

GlaxoSmithKline spa, Verona

**Industria del Farmaco e MSL.
Esiste una discussione scientifica
non promozionale?**



Verso Nuovi Modelli Commerciali...

McKinsey&Company

- It's perfectly legal to pay a physician to speak about your drug to other physicians. So when you have a new-product launch, that's the way that we educate physicians, by paying some physicians to speak.
- But if you think about this as a person who's going to that physician and thinking, "Well, Novartis paid this physician to speak about their new drug. Is that doctor prescribing it because they paid him? Or is that doctor prescribing it because that's really what's necessary for me?"
- Society's expectations about healthcare companies have shifted over time. Doing what's legal is not enough. We have to do what's right.
And so that means making some hard choices.

#NuovoModelloCommerciale 1.2016

ATTIVITA'

+ → +

1

+ → -

2

- → +

3

+ → - ...

- a. € O.S. Relatori
- b. Invito a Eventi
- c. Incentivi a ISF (2015)



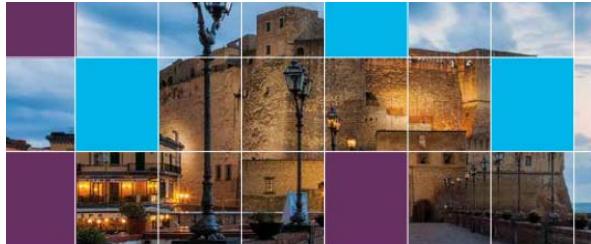
...

a. Eventi GSK

b. Multicanalità

c. IME – Independent

Medical Education



XXIX CONGRESSO NAZIONALE **SIAAIC 2016**

Società Italiana di Allergologia, Asma ed Immunologia Clinica

ALLERGY AND CLINICAL IMMUNOLOGY TOWARDS
PERSONALIZED AND SUSTAINABLE MEDICINE

NAPOLI 14/17 APRILE 2016
Hotel Royal Continental

	UNMET NEED IN ASMA E POSSIBILI RISPOSTE* Moderatori: C. Lombardi (Brescia); G. Recchia (Verona) La ricerca di precisione ed il "paziente esperto" Come cambia lo scenario della ricerca nell'asma A. Rizzi (Verona)	AUDITORIUM
16:00 - 17:00	2016x13.6%: come possiamo migliorare l'aderenza alla terapia dell'asma G. Senna (Verona)	
16:15 - 16:30	Farmacologia di fluticasone furoato e vilanterolo F. Arpinelli (Verona)	
16:30 - 16:45	Esperienza clinica e ricerca empirica: le promesse sono mantenute? O. Rossi (Firenze)	

— → + ...Mindset P2P

a. Eventi GSK

b. Multicanalità

c. IME – Independent

Medical Education

- “parla dove parlano, pubblica dove pubblicano”
- Certificazione delle conoscenze

Progetto Pharma Medical Certification Academy - Ed. III

Il progetto formativo *Progetto Pharma Medical Certification Academy - Ed. III*, organizzato in collaborazione con SIAAIC, è finalizzato al miglioramento della formazione e della comunicazione degli interlocutori delle Direzioni Mediche aziendali con il mondo clinico e scientifico appartenente all'area respiratoria.

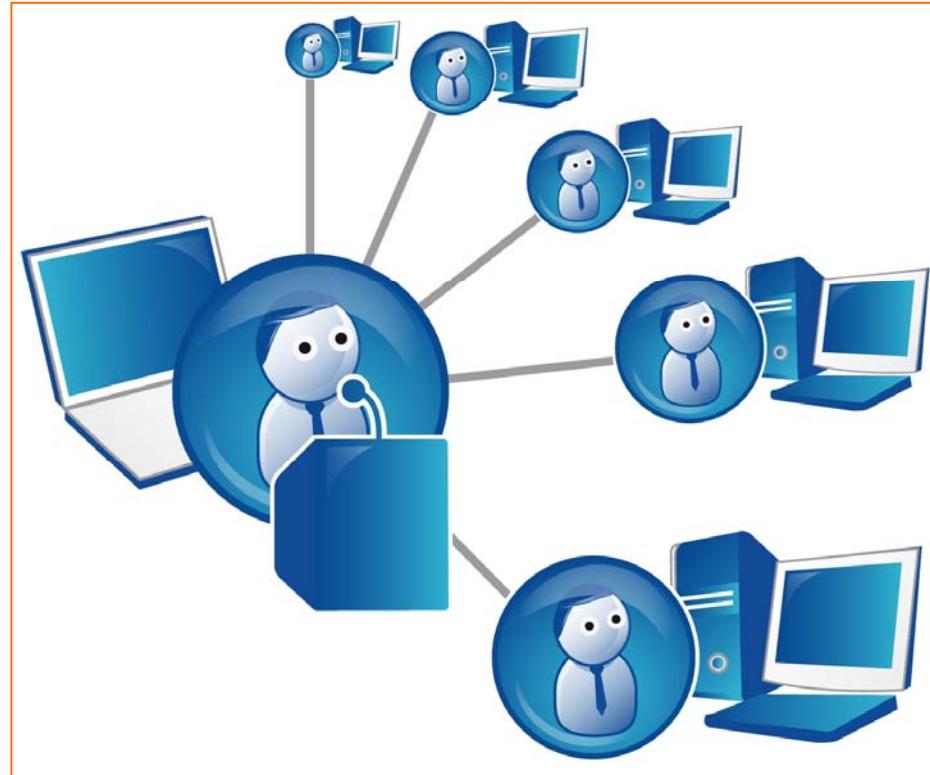
I partecipanti alla Terza Edizione della *Pharma Medical Certification Academy* hanno ottenuto, previo superamento di prova scritta e orale, la certificazione finale.

Questo progetto rappresenta una importante milestone all'interno di un percorso di certificazione iniziato nel 2015 e fortemente sostenuto dalla nostra Società: un doveroso ringraziamento a GSK che, come prima Azienda, ha supportato e creduto in questo progetto formativo.

- → +

- a. Eventi GSK
- b. Multicanalità
- c. IME – Independent

Medical Education





a. Eventi GSK

b. Multicanalità

c. IME – Independent Medical Education

The screenshot shows the GSK website's header with the GSK logo and navigation links: Chi siamo, Ricerca, Produzione, Aree di attività, Per la comunità, Lavora con, Operatori sanitari, and Pazie. Below the header, a breadcrumb navigation shows the path: Home > Operatori sanitari > IME 2017. The main content area is titled "IME 2017" and discusses the company's engagement with the medical community. On the left, there is a sidebar with links for "HCP Engagement Initiative", "IME 2017" (which is currently selected), "Regolamento/Bando Area Terapeutica Immune Rare Diseases", "Modulo adesione IME", "TPE", "Borse di studio", "Regolamento", "Bando", and "Application form".

Regolamento/Bando Area Terapeutica Immune Rare Diseases

[Regolamento Bandi IME-ECM per sostegno GSK \(1/2017/IRD\)](#)

Art. 1 - I Bandi IME-ECM GSK

Periodicamente sul sito www.gsk.it verranno pubblicati i Bandi IME-ECM GSK.

Con la pubblicazione del Bando, GSK rende nota la sua intenzione di valutare Proposte di programmi formativi ECM onde sostenere quelli che saranno giudicati scientificamente più validi.

Le Proposte da parte dei Provider dovranno rispettare i Requisiti minimi delle Proposte IME-ECM, come di seguito descritti.

#NuovoModelloCommerciale



GSK's new 'ethical' customer approach: Is it delivering?

A review, analysis and key lessons



Skepticism around the new model

What do other pharma companies and key opinion leaders expect, the changes met with a great deal of both skepticism. The concerns of industry insiders fell broadly into four areas:

1. Why change the sales model entirely?
2. Is GSK simply overcompensating for previous mistakes?
3. What is the risk to R&D budgets?
4. Can this model be sustained with the upcoming changes?

Will the industry follow GSK's lead?

"[The] American Association of Retired Persons (AARP) is hopeful that these business practices will become a standard across the industry," says AARP's Public Policy Officer.

However, while many share AARP's hopes, there is little sign that the industry is following GSK's lead. "I don't think this is a trend," says John LaMatta. "I don't see it catching on, especially if GSK sales go up, but if it does not work, I think it will catch on."

"I certainly won't be rushing to do what GSK is doing until I know more about whether it is working or not," says Stewart Adkins. "I think you can expect to see any change. You have to look at sales by country or region by region to see if there was any response or a change in how you do things and the sales output." A host of variables will affect the success of the new model, including the size of the market, the complexity of the product, and the competitive landscape.

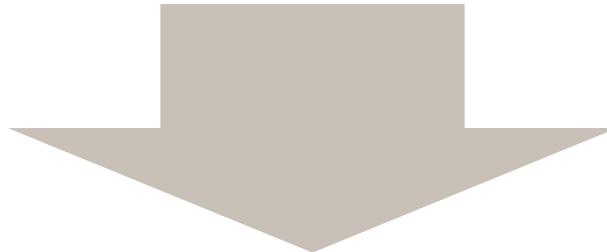
Patient Engagement - 1

1. Ascolto attivo, Insights, Click2Chat

a. *Insight pazienti su esperienza, patologia e prodotti*

2. Costruzione ed esecuzione dei processi aziendali

a. *Stage Patient Engagement*



engagement di singoli / gruppi pazienti
non organizzati in ADP

Patient Engagement - 2

1. Identificazione

principio della volontarietà

- a. selezione da parte di soggetti terzi (HCP / HCO / ADP)
- b. invito pubblico
 - i. affissione pubblica
 - ii. web aziendale
- c. database pazienti aziendale (staff GSK)

2. Invito

- a. lettera
- b. descrizione iniziativa

Patient Engagement - 3

3. Attività

- a. Testimonianza (eventi interni / eventi esterni)
- b. Acquisizione di informazioni
- c. Acquisizione di insight
- d. Acquisizione di advice

4. Onorario e Rimborso spese

- a. Quando appropriato, tariffario

5. Contratto

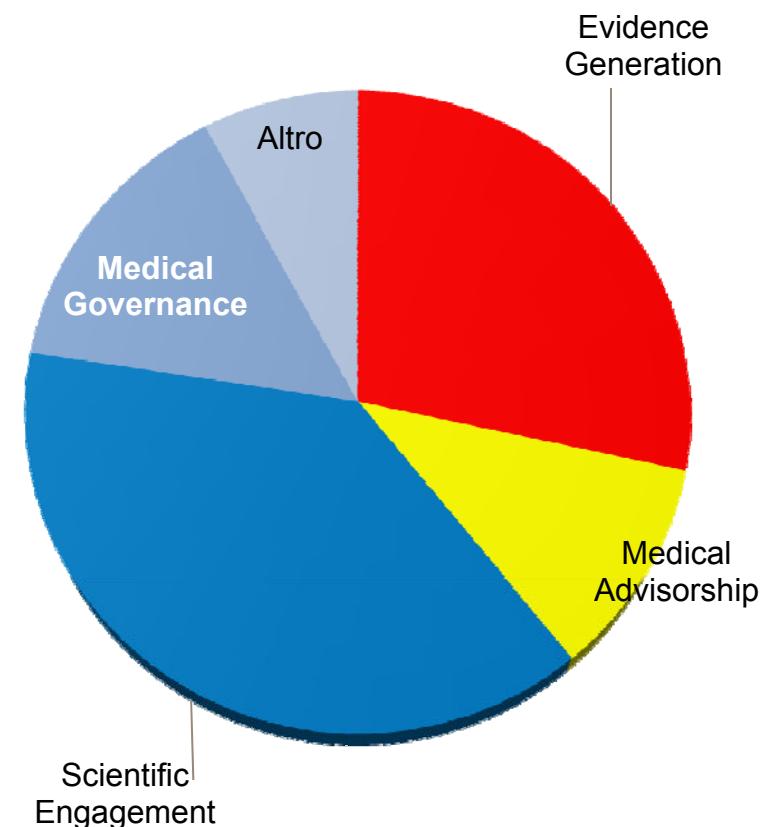
- a. Incontro
- b. Viaggio
- c. preparazione

Risk Management



Compliance vs Medical Governance

- I. Management Monitoring
- II. Independent Business Monitoring
- III. Independent Assurance
- IV. Regulatory Inspection



Grazie ...



Giuseppe Recchia
@G_Recchia

Le imprese farmaceutiche che nel 21[^] secolo mantengono il modello del 20[^] sono destinate a fare la fine del Dodo...#NuovoModello #patient1st

Translate from Italian



Pricing's dodos

BRIAN O' SMITH

Mylan isn't alone in its outdated practices

As often happens, events in my three months of work encouraged this month to illuminate a phenomenon that can truly be explained by evolutionary science. One of my research interests is focused on the evolution of market structures and policies. One of my current advisory roles involves the market access strategy for a large but aging brand. And, as I prepared for an interview about my imminent new book, I took the news story about Mylan's EpiPen as an example. In all three parts of my work, I was observing real-world behaviour that perfectly illustrates the evolution of the industry. As usual, allow me to digest into the science before I return to the practical implications.

Perhaps the most well-known example of biological extinction is the dodo, that giant flightless bird that was once endemic to

'Companies that persist in 20th century behaviour will, in the 21st century, go the way of the dodo'

We see the same evolutionary forces at play in pharmaceutical markets.

But the parallel goes further than just the name of the company, which has been around since 1881. The lesson of the dodo is that super-adaptation to one environment, coupled with an inability to adapt quickly, is a huge disadvantage when the environment changes.

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@ G_Recchia



Giuseppe Recchia
@G_Recchia

Dodo (*Raphus cucullatus*): uccello columbiforme dell'isola di Mauritius. Si estinse rapidamente nel 17[^]sec al cambiamento del suo ecosistema