



Società Italiana per Studi di Economia ed Etica sul Farmaco e
sugli Interventi Terapeutici



SEMINARIO DI AGGIORNAMENTO GOVERNANCE DEI PROCESSI AZIENDALI

IL RUOLO DEL MEDICAL AFFAIRS

Roma, 26 Gennaio 2017

I NUOVI RUOLI NEL MEDICAL AFFAIRS E IL LORO GOVERNO

Giovan Battista Leproux

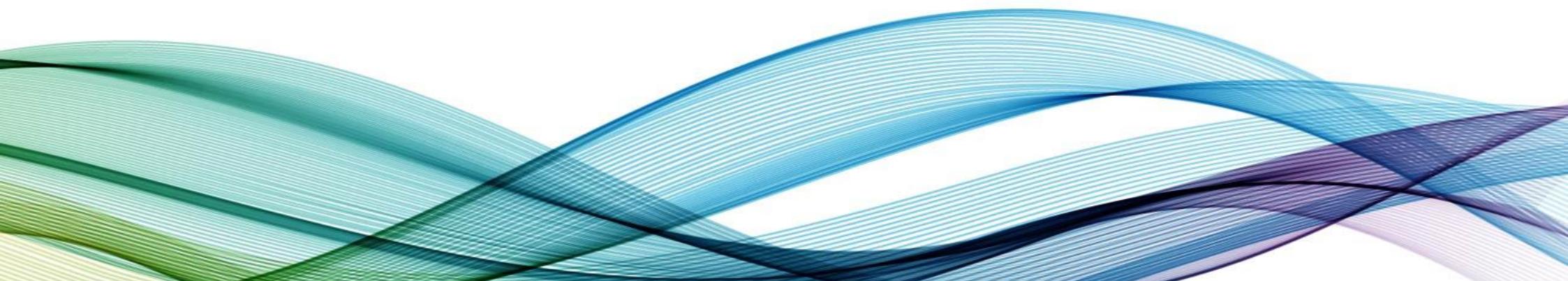
**Views expressed during the presentation are solely those of the presenter
and not his employer (BMS)**



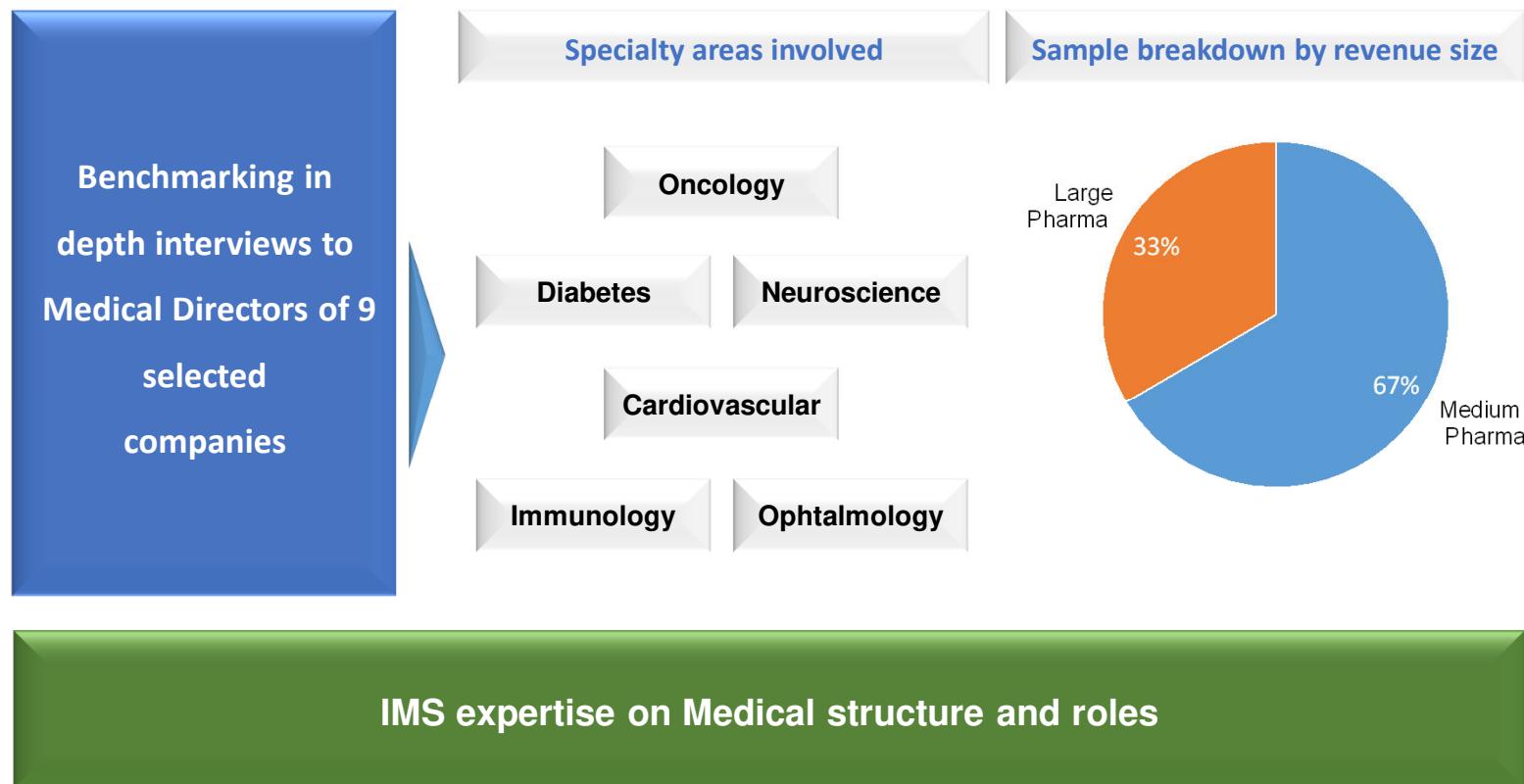
QuintilesIMS™

Key Medical Trends in Italy QuintilesIMS survey

Milan, 02.12.2016



To understand key trends of Medical organizations, we leveraged our medical expertise and performed a survey in 2016
The sample



The weight and role of Medical Affairs differs from companies with new launches to those with an established portfolio





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Human medicines highlights 2016

81
Positive
opinions

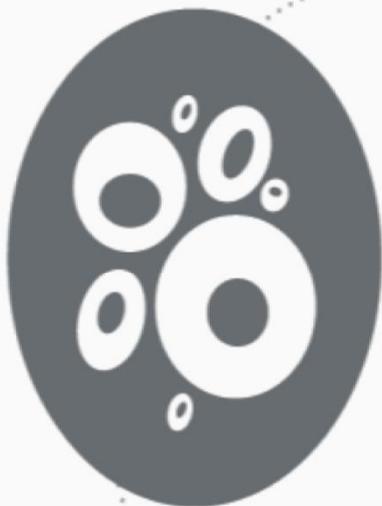
27
New active
substances

2
Negative
opinions*

16
Withdrawn
applications

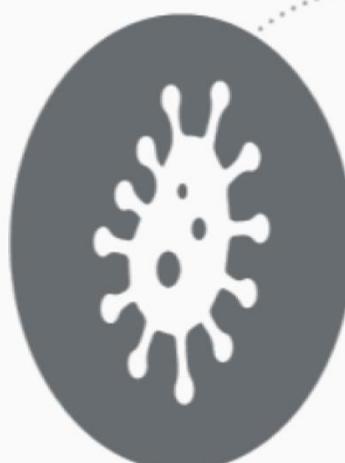
Medicines recommended for approval in 2016

Cancer



- Alecensa ●
Bortezomib Hospira
- Bortezomib SUN
- Cabometyx ●
- Darzalex ●●●
- Empliciti ●
- Ibrance
- Kisplyx ●
- Lartruvo ●●●
- Ledaga ●●
- Lonsurf
- Ninlaro ●●
- Onivyde ●
- Pemetrexed Fresenius Kabi
- SomaKit-TOC ●
- Truxima (biosimilar)
- Venclyxo ●●

Infections



- Atazanavir Mylan
- Darunavir Mylan
- Descovy
- Emtricitabine / Tenofovir disoproxil Mylan
- Emtricitabine / Tenofovir disoproxil Krka
- Emtricitabine - Tenofovir disoproxil Zentiva
- Epclusa ●
Odefsey
- Tenofovir disoproxil Mylan
- Tenofovir disoproxil Zentiva
- Vemlidy
- Zavicefta
- Zepatier
- Zinplava

● Orphan medicine
● Conditional marketing authorisation

● Accelerated assessment
● Approval under exceptional circumstances

The medicines that contain a new active substance are highlighted in blue

Cardiovascular



- Amlodipine-Valsartan Mylan
- Inhixa (biosimilar)
- Ivabradine JensonR
- Ivabradine Zentiva
- Mysildecard
- Neparvis
- Uptravi**
- Tadalafil Generics
- Thorinane (biosimilar)

Rheumatology



- Flixabi (biosimilar)
- Lifmior
- Movymia (biosimilar)
- Nordimet
- Olumiant**
- Sialanar
- Terrosa (biosimilar)
- Truberzi**

Metabolism



- Chenodeoxycholic acid
- Cystadrops
- Fiasp
- Galafold**
- Glyxambi
- Lusduna (biosimilar)
- Qtern
- Suliqua

Haematology/ Haemostaseology



- Afstyla**
- Alprolix**
- Coagadex
- Idelvion**
- Vihuma
- Zalmoxis**
- (advanced therapy)

Hepatology/ Gastroenterology



- Enzepi
- Ocaliva**
- Palonosetron Accord
- Palonosetron Hospira

Pneumology/ Allergology



- Aerivio Spiromax
- Airexar Spiromax
- Cinqaero**
- Granpidam

Neurology



- Ongentys**
- Pregabalin Zentiva k.s.
- Rasagiline Mylan
- Zinbryta

● Orphan medicine

● Conditional marketing authorisation

● Accelerated assessment

● Approval under exceptional circumstances

The medicines that contain a new active substance are highlighted in blue

Cambiato il contesto: la sfida del cambiamento

For years, pharmaceutical companies have deployed their Medical Affairs workforces to help physicians improve patient care through the safe and appropriate use of drugs.

While these resources are considered valuable, customers rarely see them as critical to improving population health outcomes



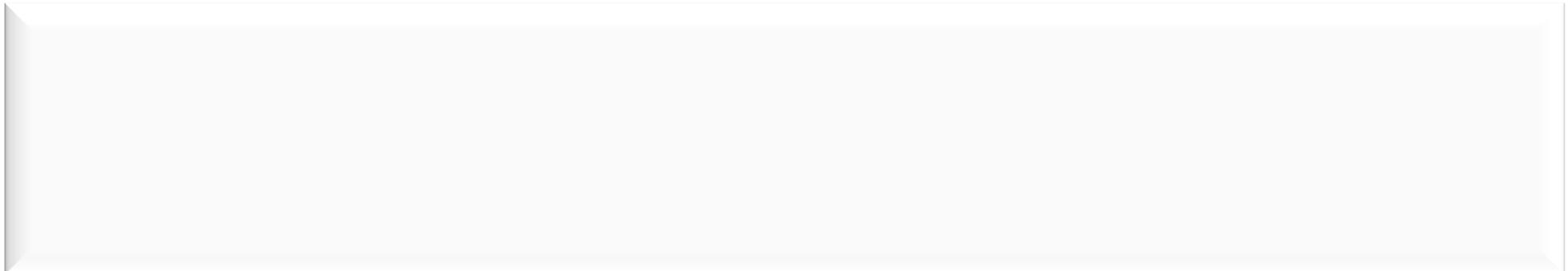
That's about to change

Cambiato il contesto: l'interlocutore non è più solo il medico

Nuovi e importanti protagonisti del «sistema salute» sono oggi interlocutori primari per la Direzione Medica

- Pagatori (dalla CPR di AIFA ai vari Comitati Regionali)
- Farmacisti
- Personale ospedaliero non medico (Tecnici di Laboratorio,Infermieri)
- Le associazioni dei pazienti

Ciascun gruppo richiede una «modulazione» specifica della comunicazione



Cambiato il contesto: incremento dell'attenzione da parte delle autorità regolatorie

Incremento dei limiti di interazione tra personale delle Società Farmaceutiche e personale del Sistema Sanitario Nazionale



Necessità di ottimizzare le interazioni : il Key Account Management

Medical Affairs: da un ruolo operativo ad un ruolo strategico

Medical Affairs professionals can serve a **strategic role** and help inform **value discussions** by sharing the **most relevant and trustworthy** information with healthcare teams.

I ruoli che cambiano

- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource
- Biomarkers Specialist
- Scouting

Field Medical Operating Principles

Medical professionals with advanced medical and scientific education, and often with extensive clinical experience within one or more therapeutic area(s)

Communicate complex scientific and medical information on disease areas in which the company is involved, and on products, to support the safe, effective and appropriate use of approved medicines (internally: Brand Teams, Externally: HCPs)

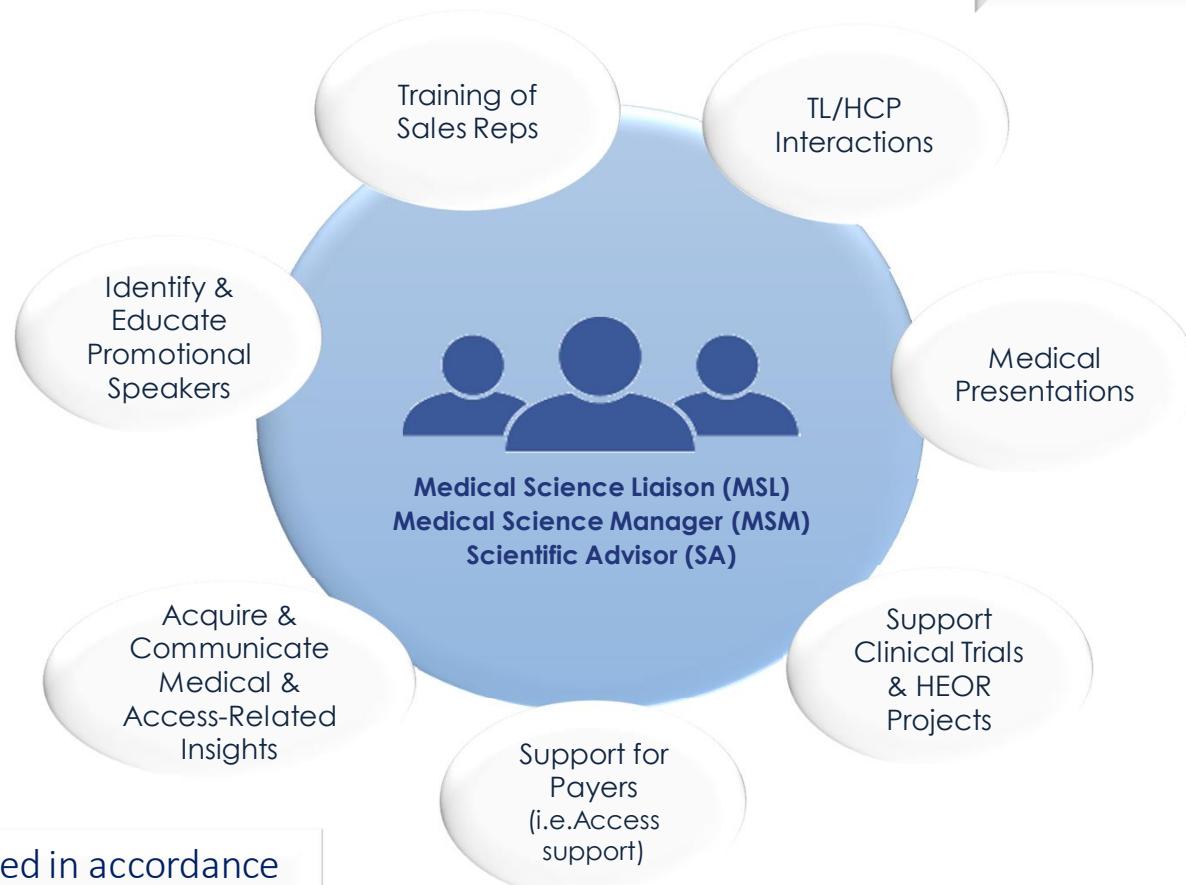
Field Medical

Like all employees, Field Medical staff must comply with all applicable laws, regulations, and company policies and procedures

Interact with HCPs in their own clinical environment on a regular basis enabling to collect insights on current healthcare practices

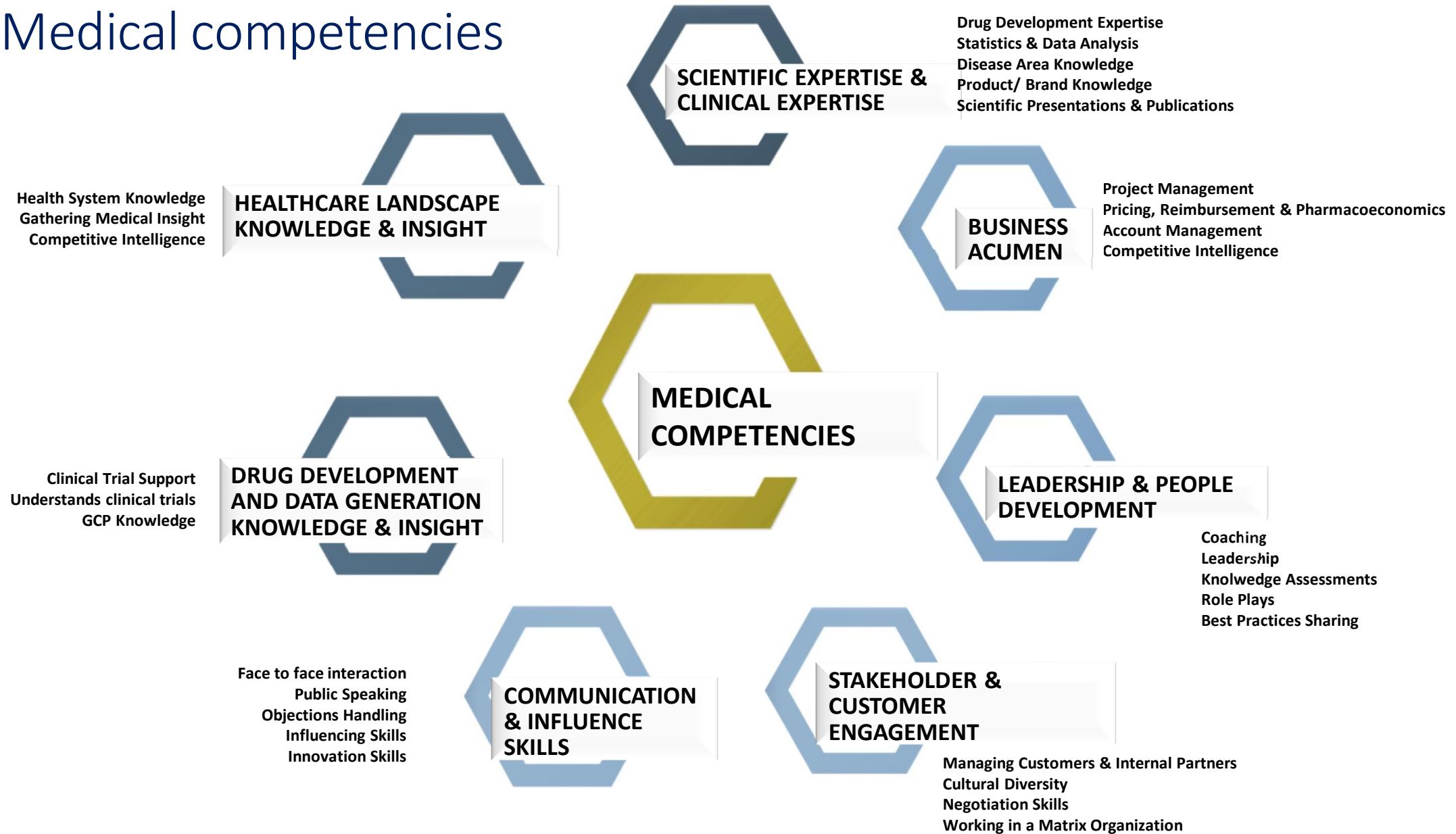
Key Field Medical Activities @ BMS

Proportion of time spent on each activity is dependent on specific therapeutic area objectives and product life-cycle



All activities to be conducted in accordance with all applicable laws, codes, regulations and internal procedural documents

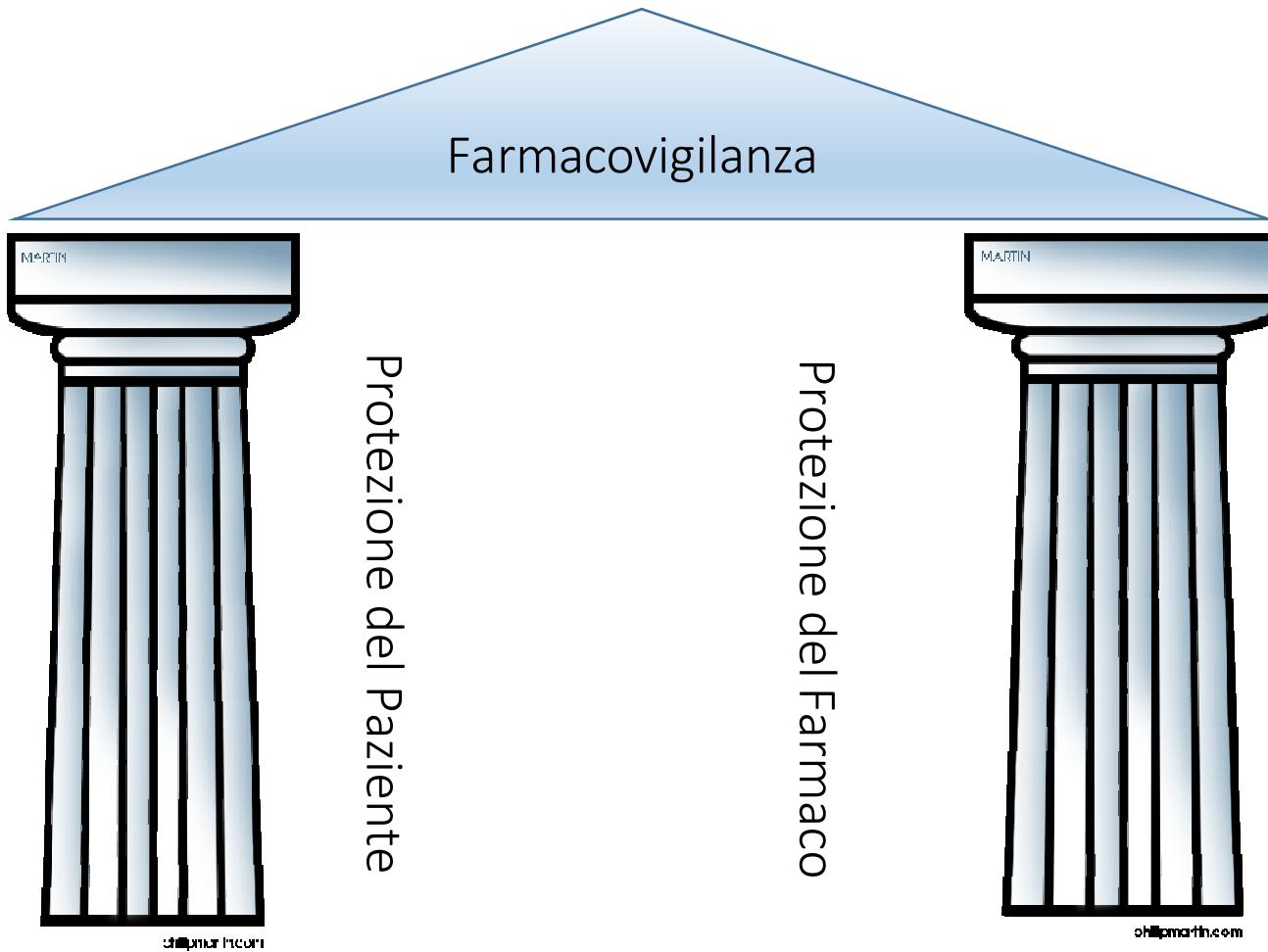
Medical competencies



I ruoli che cambiano

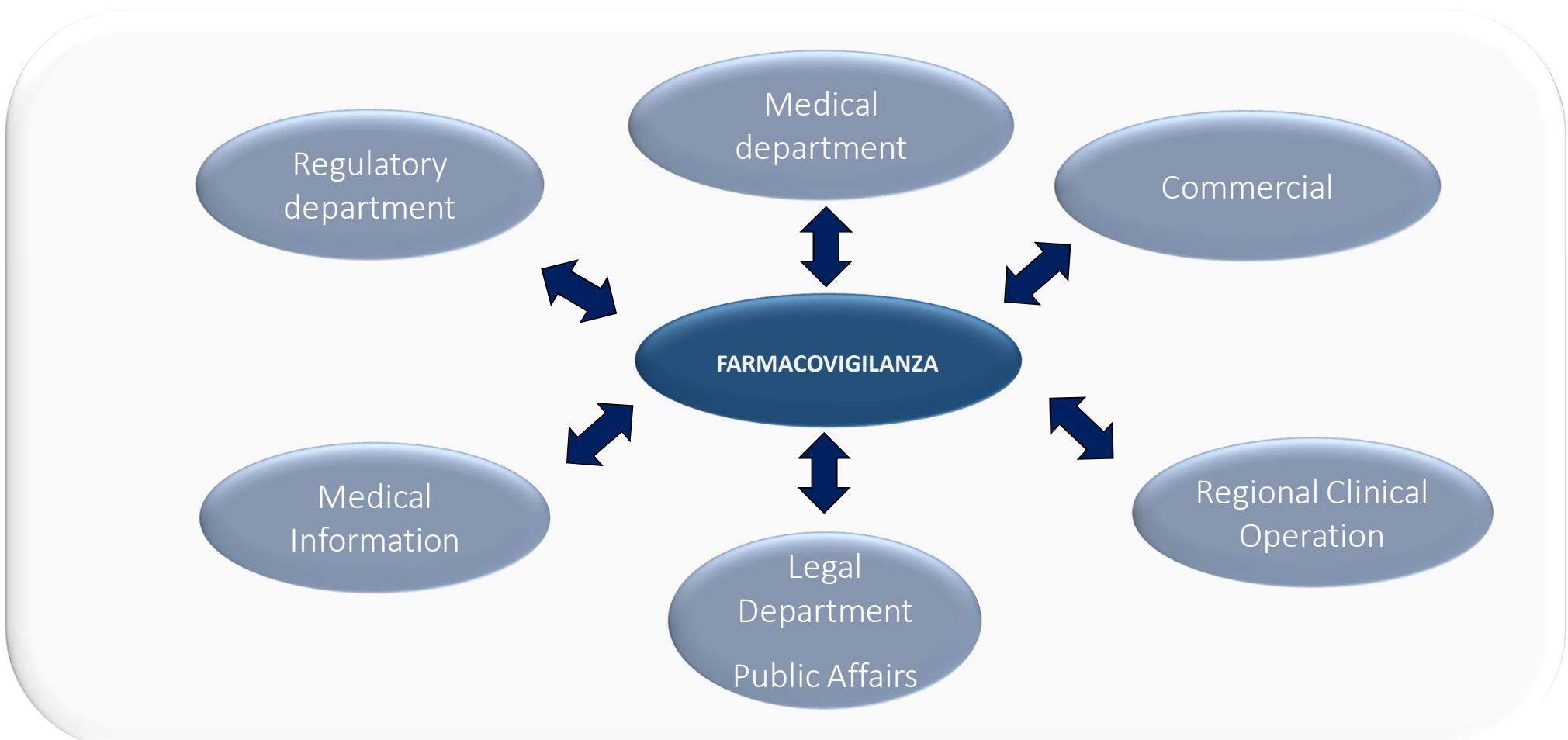
- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource
- Biomarkers Specialist
- Scouting

Farmacovigilanza: Imperativo etico e strategico



MISSION FVG

Interazioni Farmacovigilanza



Risk Management Plan – Come nasce

PROFILO DI SICUREZZA
NESSUNA
PREOCCUPAZIONE



ATTIVITA' ROUTINE RISK
MINIMIZATION
(RCP; Sistema FVG standard)

Marketing Authorization



PROFILO DI SICUREZZA CON
- RISCHI IDENTIFICATI
- RISCHI POTENZIALI
- INFO MANCANTI



PASS
Post Authorization
Safety Studies
Long Term,
Studi Geriatrici,
Pediatrici

ATTIVITA'
ADDITIONALI
RISK MINIMIZATION
(HCP Brochure ,
Patient Alert Card,
DHCP Letters, etc.)

PV – Internal Awareness Activities

Style Videos



Multiple choice test for all employees – Three Smartbox Prize

Out of office Message

*bilingual text with info for
reporting AE*



I ruoli che cambiano

- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource
- Biomarkers Specialist
- Scouting

Importanza della Medical Information

Objectives of WW Approach

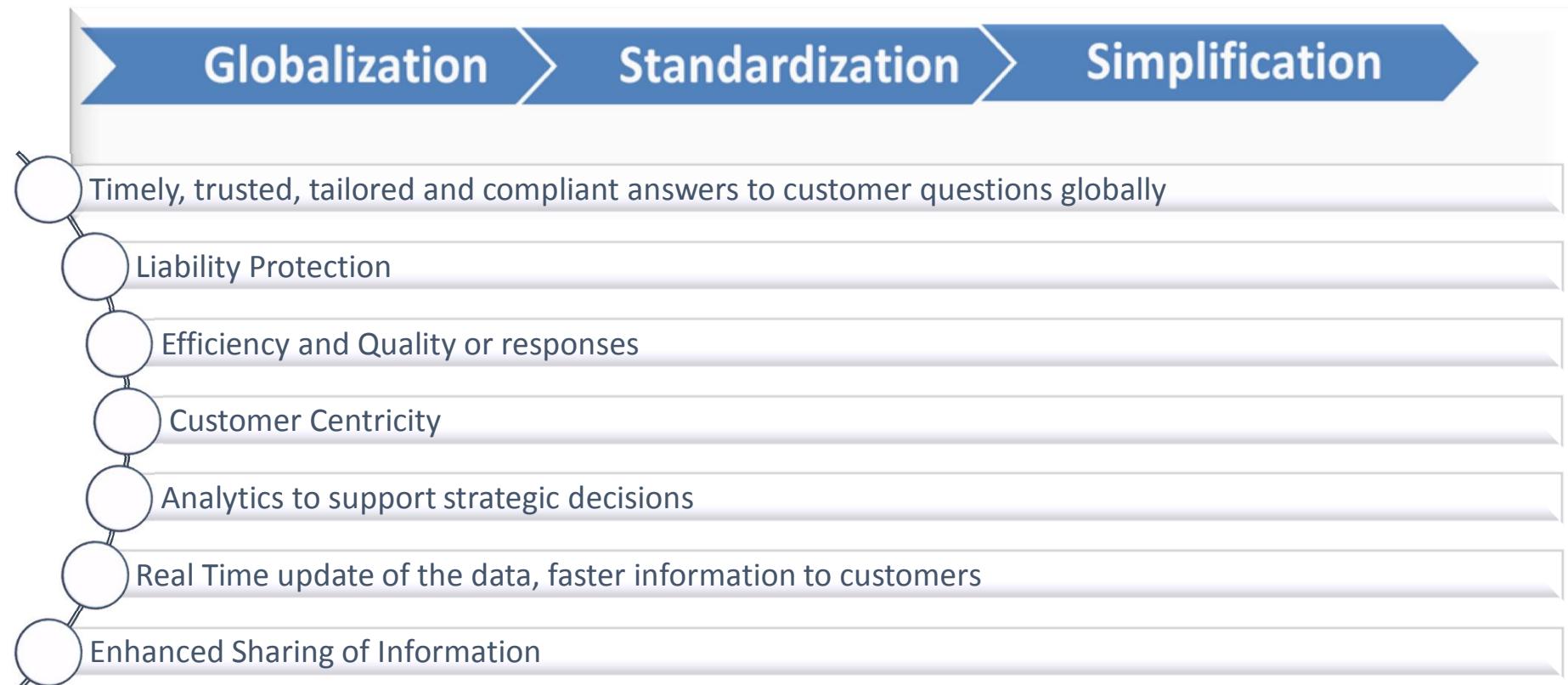
What: Share best practice and understanding what are the customer insights we need to action across markets. Being prepared.

How: A minimum of monthly focus coordinated across the WW team to ensure all focused on Speed to Patient, External Focus

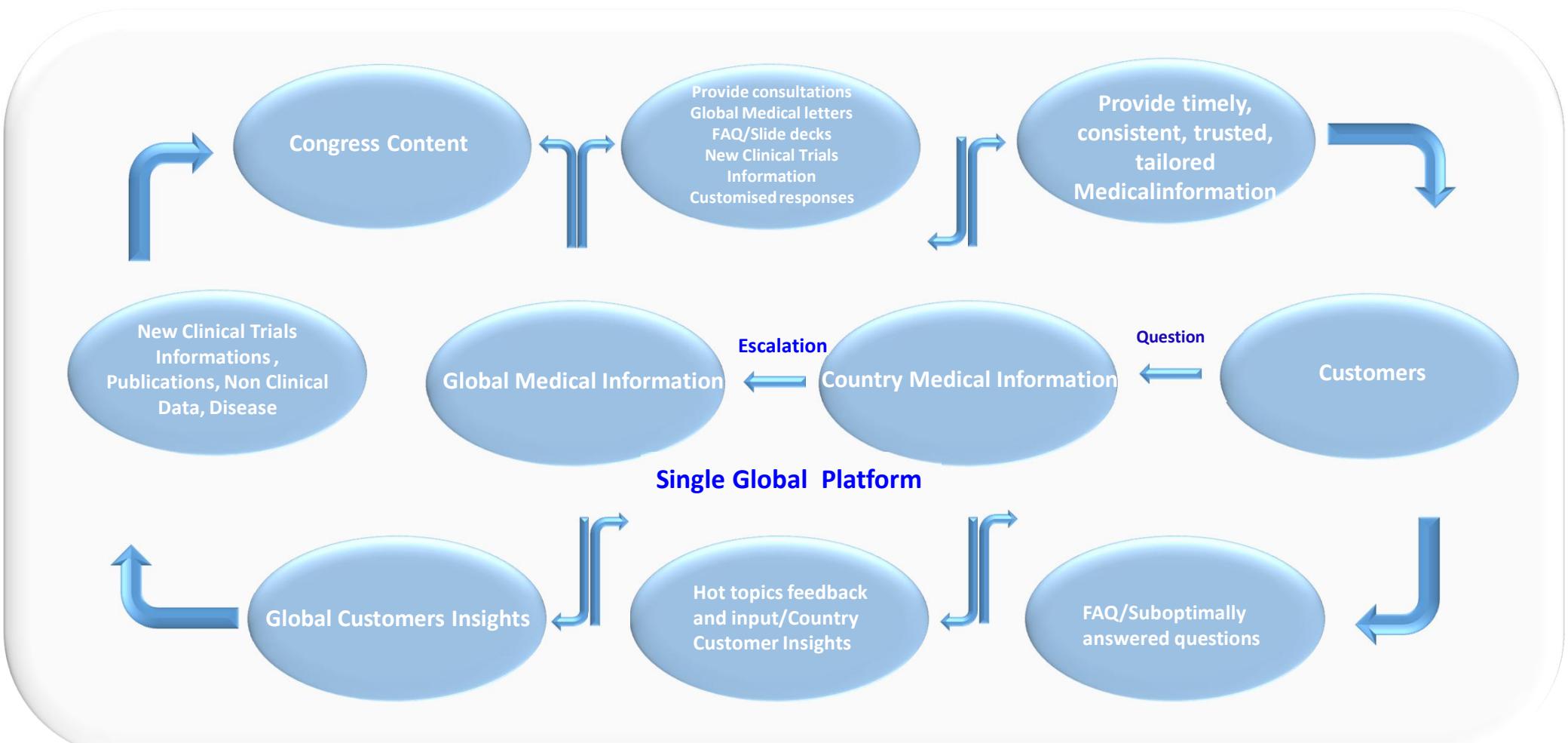
Why: Clear understanding of TA priorities and knowledge across every part of WW MI to benefit our customers

Importanza della Medical Information

One global model based on core principles



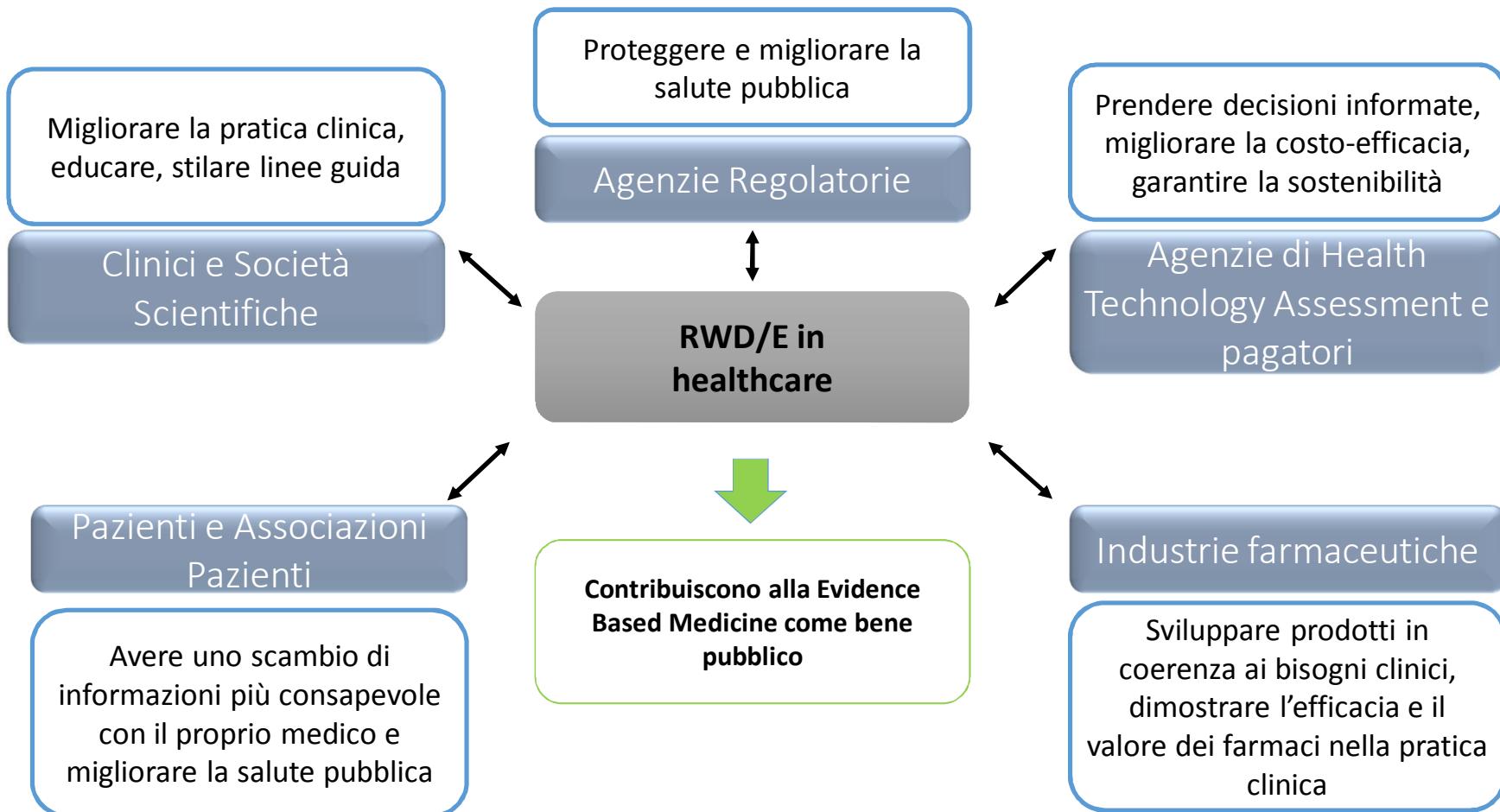
How do we work together



I ruoli che cambiano

- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource Manager
- Biomarkers Specialist
- Scouting

Chi ha bisogno di RWE?



Definizioni: RWD vs RWE

RWD
(real-world
data)

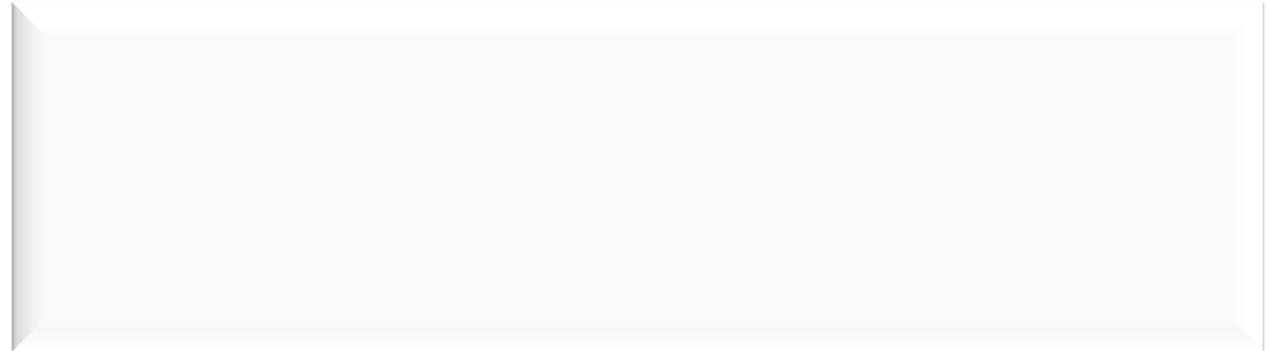
RWD are data that are collected outside traditional controlled clinical interventional trials under real-life practice circumstances.* The scope of data can be product-specific, but can also be on a disease area level

RWE
(real-world
evidence)

RWE is RWD that has been organised to inform a conclusion or judgment (e.g. comparative effectiveness research where data on active treatments in the ‘real-world’ setting is transformed into actionable intelligence)

* Definition consistent with ISPOR Real-World Task Force Report and European Forum ‘Relative Effectiveness’ Working Group

Il valore di generare RWE è triplice



I ruoli che cambiano

- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource
- Biomarkers Specialist
- Scouting

Biomarkers, a growing field in Immuno-Oncology



Physicians' Needs



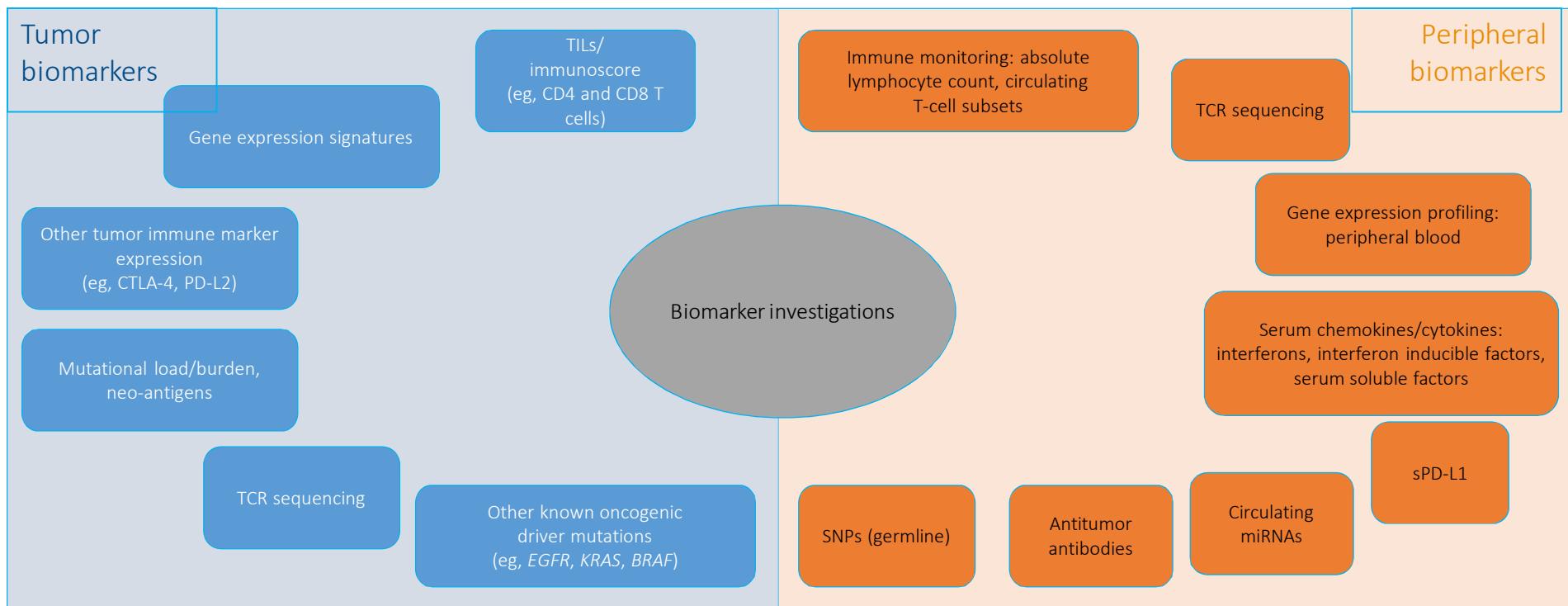
Drug Development



Economic Burden



Additional Exploratory Biomarkers Under Investigation for I-O Therapies¹⁻¹²



1. Sosman JA et al. Poster presentation at ASCO 2013. TPS3114.
2. Choueiri TK et al. Oral presentation at ASCO 2015. 4500.
3. Clinical Protocol CA209009.
4. Lawrence MS et al. *Nature*. 2013;499(7457):214-218.
5. Antonia SJ et al. Poster presentation at WCLC 2013. P2.11-035.
6. Weber JS et al. *Lancet Oncol*. 2015;16(4):375-384.
7. Brown SD et al. *Genome Res*. 2014;24(5):743-750.
8. Postow MA et al. *J Transl Med*. 2014;12(suppl 1):O8.
9. Komatsu N et al. *Cancer*. 2012;118(12):3208-3221.
10. Wang Z et al. *Med Hypotheses*. 2013;81(1):41-43.
11. Luborsky J et al. *Am J Reprod Immunol*. 2005;54(2):55-62.
12. Schneider BP et al. *Lancet Oncol*. 2012;13(10):e427-e436.

I ruoli che cambiano

- Field Medical organization
- Farmacovigilanza
- Medical Information
- Outcome Resource
- Biomarkers Specialist
- Scouting

Sfide e opportunità: lo scouting

PHARMACEUTICALS

Drug buddies

The pharmaceutical industry is seeking stronger ties with academia in a bid to speed up drug development.

23 JUNE 2011 | VOL 474 | NATURE | 433

Sfide e opportunità: lo scouting

Le biotech Farma sono una realtà consolidata in Italia

Le 199 aziende del Farmaco biotech hanno registrato un aumento del fatturato del 4,3% (€ 7.302 milioni nel 2013 rispetto ai € 7.004 milioni nel 2012)

L'oncologia è l'area terapeutica con il maggior numero di progetti di R&S (130) la maggior parte dei quali si trova nelle fasi avanzate di sviluppo (66,9% in Fase II e III).la pipeline del Farmaco biotech si concentra principalmente su: anticorpi di tipo monoclonale (33%), prodotti a basso peso molecolare (28%) e proteine ricombinanti (12%)

Science does not stand still

....It's not too early for pharmaceutical leaders to start thinking about how they can position their Medical Affairs organizations to have an even greater impact on the healthcare system.

Refine the role of Medical Affairs from disease and product specialists to curators and connectors of outcome-focused Information is a **first step**.

The **second step** is for leaders to honestly assess their workforce's capacity to make the transition.

- Do they have the right number of customer-facing resources?
- Do they have the right talent and skills sets to address the growing B2B nature of customer interactions?
- Do they have the right metrics to measure the value-adding activity of Medical Affairs?

Ringraziamenti

- Paolo Beccaro per la Field Medical Organization
- Francesco De Solda per l'Outcome Research
- Eliana Maci per i Biomarker
- Marialaura Papetti per la Medical Information
- Loris Riva per la Farmacovigilanza
- e Enrica Palladino per la revisione generale