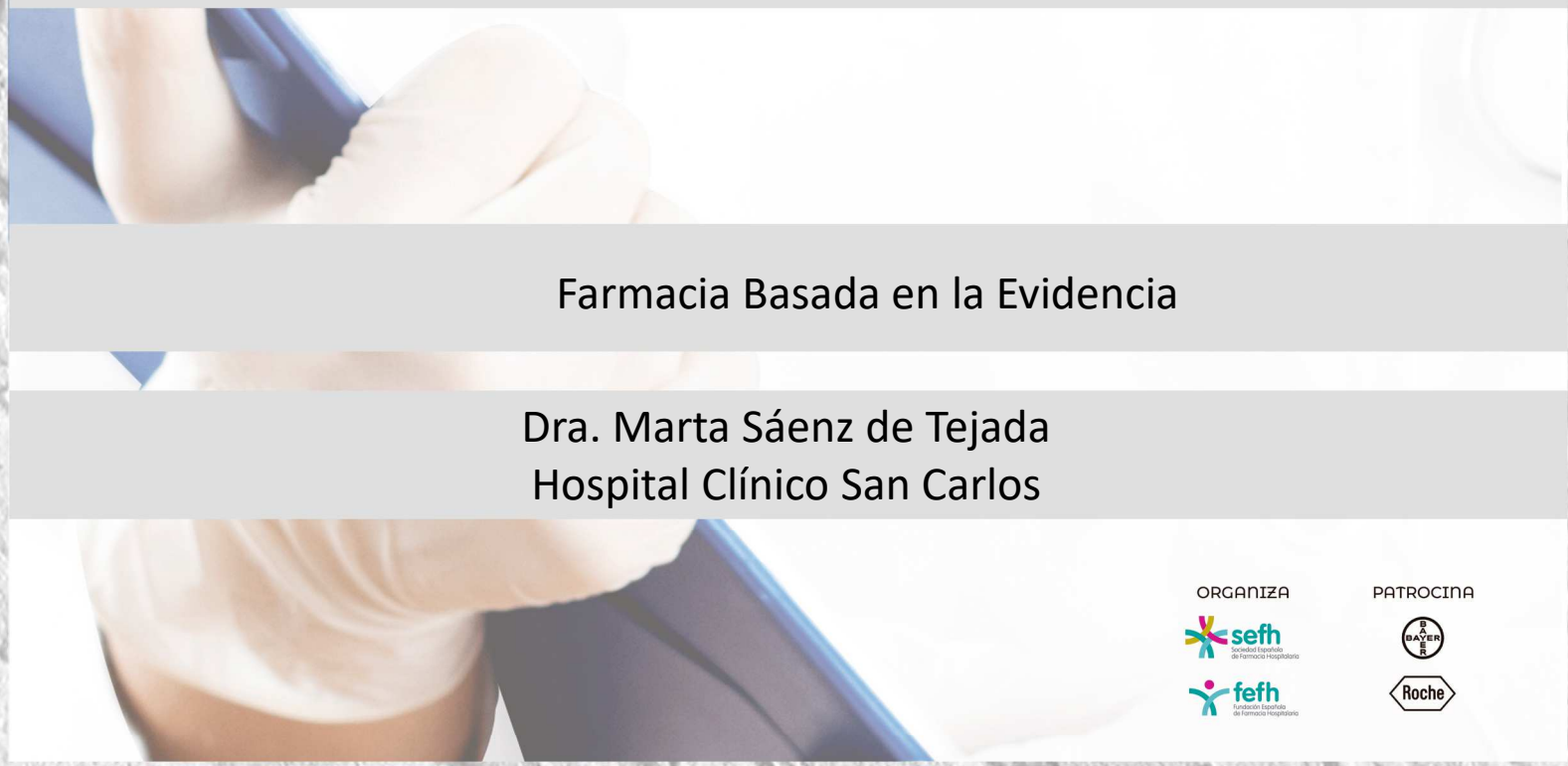
JORNADA POST EAHP

Farmacia Basada en la Evidencia

Dra. Marta Sáenz de Tejada
Hospital Clínico San Carlos



ORGANIZA

sefh Sociedad Española de Farmacia Hospitalaria

fefh Fundación Española de Farmacia Hospitalaria

PATROCINA

BAYER

Roche

El programa

	Pfizer "Non-Vitamin K antagonist Oral Anticoagulants (NOACs): Advancing patient care in stroke prevention and venous thromboembolism"	G4
	Leo Pharma "Anticoagulation in active cancer: Special considerations"	F4
13.30 - 15.00	Lunch	Hall B
		ctice. What changed with	Hall B - Booth no 26
16.00 - 17.00	Coffee break	Hall B
17.00 - 18.30	Seminars	
	Seminar ER1 - Clinical Trials in Paediatric Haemato- to participate ACPE UAN: 0475-0000-18-024-L04-P. A knowledge b M-B. Aretin; F. Engels	
	Seminar PC2 - Hospital mergers and the centralisat ACPE UAN: 0475-0000-18-016-L04-P. A knowledge b A. Vermes; S. Crauste-Manciet	
	Seminar IG2 - The productive pharmacist - Process ACPE UAN: 0475-0000-18-011-L04-P. A knowledge b V. Zardet; M. Frachette	
	Seminar SPD2 - Bridging the efficacy / effectiveness ACPE UAN: 0475-0000-18-014-L04-P. A knowledge b A. Gouveia; N. Groessmann	
	Workshop 1 - The pharmacist's role in the drugs an ACPE UAN: 0475-0000-18-027-L04-P. An application N. Martinez-Lopez de Castro; H. Plet	

23rd Congress of the European Association of Hospital Pharmacists

Gothenburg, Sweden, 21-23 March 2018

	Seminar IG1 - The efficient pharmacist - Prioritising tasks and designing processes ACPE UAN: 0475-0000-18-009-L04-P. A knowledge based activity. R. Fernandes; A. Jacklin	F2+F3
	Seminar SPD1 - Medicines shortages - A reality check? ACPE UAN: 0475-0000-18-013-L04-P. A knowledge based activity. T. Hoppe-Tichy; N. Linde-Laursen	F5
	Seminar PC1 - Clinical trial regulation and ethical committees ACPE UAN: 0475-0000-18-015-L04-P. A knowledge based activity. I. Krämer*; C. M. Romeo Casabona	A3
	Seminar PC3 - Hospital pharmacists involved in ATPM and in Risk Assessment ACPE UAN: 0475-0000-18-017-L04-P. A knowledge based activity. A. De Goede; K. Saadat	G3
	Seminar CPS1 - Managing polypharmacy - Thinking outside the box ACPE UAN: 0475-0000-18-010-L04-P. A knowledge based activity. M. Wilson; C. Morrison	G1+G2
	Seminar PQ2 - Ready to administer drugs - Is everything under control? ACPE UAN: 0475-0000-18-023-L04-P. A knowledge based activity. S. Sauer; O. Delgado Sánchez*	A5
	Workshop 2 - Assessment and clinical importance of pharmacists recommendations ACPE UAN: 0475-0000-18-028-L04-P. An application based activity. H. Toss; U. Gillespie;	J2

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Normativa aplicable EC

- CH-GCP Guidelines

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

- EudraLex Volume10, Clinical Trials Guideline: https://ec.europa.eu/health/documents/eudralex/vol-10_en

- Guidance on Investigational Medicinal Products (IMPs) and "non investigational medicinal products" (NIMPs)

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/imp_03-2011.pdf

- **Regulation (EU) No 536/2014** of the European Parliament and of the Council **of 16 April 2014 on clinical trials of medicinal products for human use**

- **RD 1090/2015 por el que se regulan los EC con medicamentos**

➢No aplica a estudios de no intervención

➢No aplica a estudios con PS

Principios éticos
Metodología
Aspectos legales

+

Informes de seguridad periódicos
Aconteciomientos adversos severos

Good reasons for participation as pharmacist in the Research Ethics Committee

- Placement of pharmaceutical aspects
- Placement of real-life aspects

- Thinking out of the box
- Personality development
- Volunteer spirit activity for patients

- Development of better understanding for the needs of clinical reseachers
- Reputation for pharmacy profession
- Keeping pharmaceutical knowledge up-to-date

Comité ética clínica

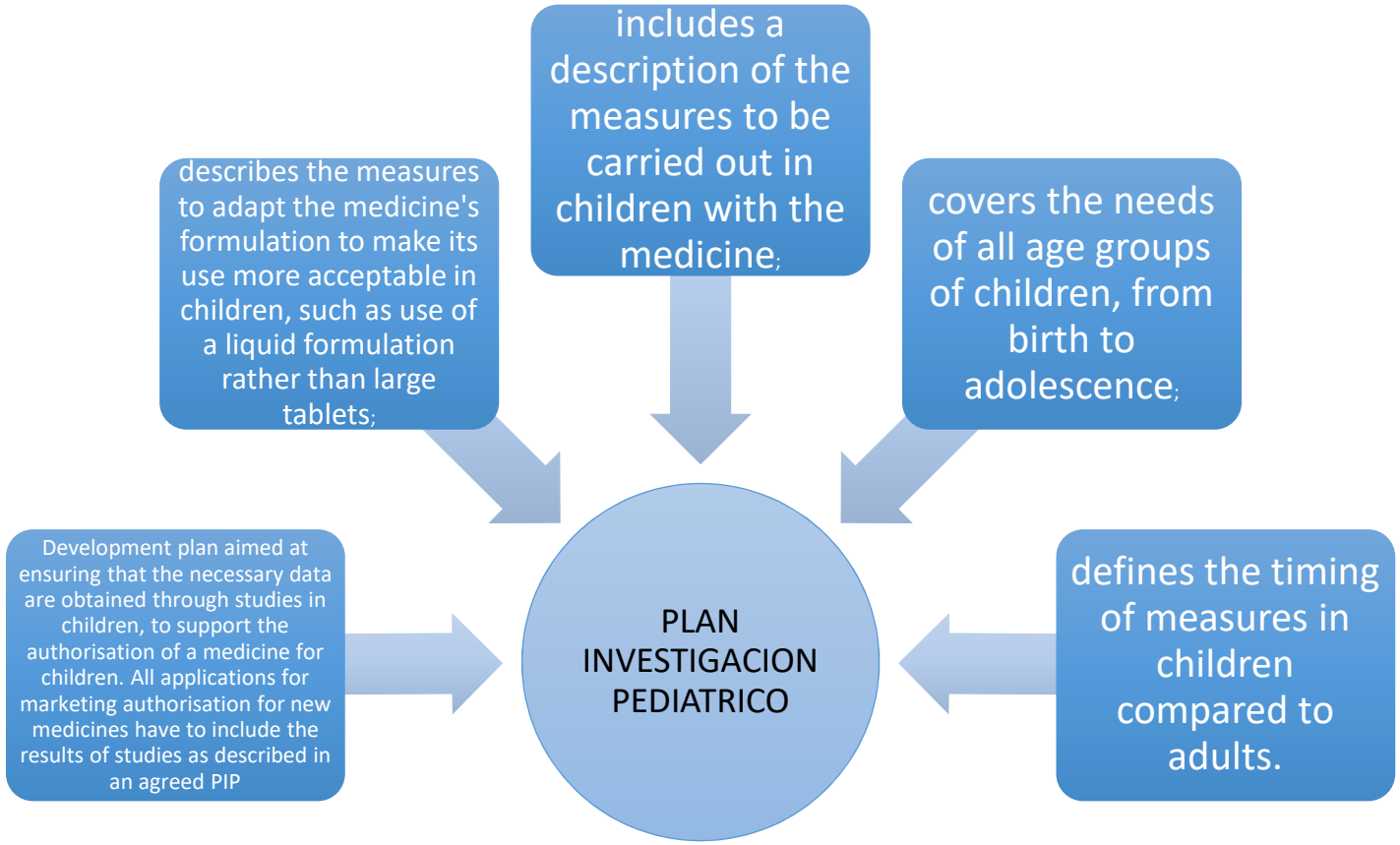
Duties of the Clinical Ethics Committee

- Education and continuing education of the hospital staff regarding clinical ethics
- Development of local guidelines for patient-oriented procedures based on ethical principles
- Consultation of the board of directors and medical directors of the clinics regarding ethical issues in medical treatment and nursing care
- Ethics consultation in individual patients requested by physicians, nurses, patients or there families/caregivers

Procedures of the Clinical Ethics Committee

- Monthly meetings
- Members: medical professionals, nurse professionals, catholic and protestant pastoral caregivers, hospital social workers, legal professional, pharmacist
- Reflection on recent patient-individual consultations
  exchange of views (e.g. religious, cultural aspects)
  conflicts with the advance directive
- Discussion of new regulations and court judgements regarding treatment of patients

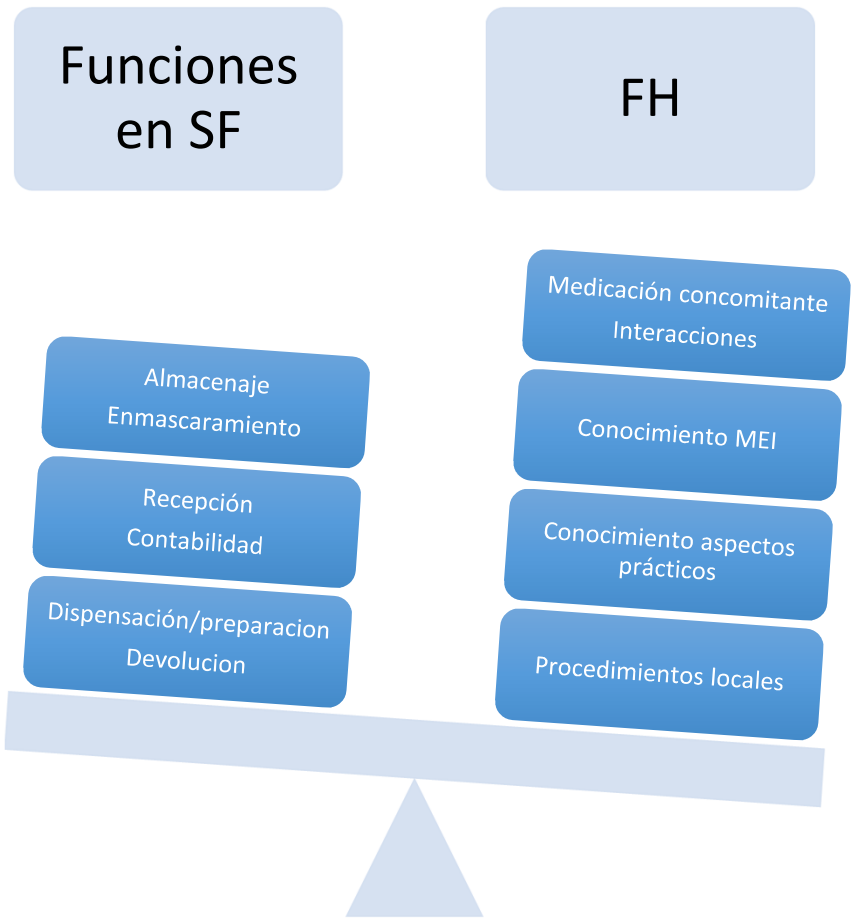
Plan investigación pediátrico (PIP)



10- year report to the European Commission

- 260 new medicines for use by children (indications & marketing authorisations).
- 83 oncology PIPs for 68 anti-cancer medicines. 5 new anti-cancer medicines authorized since Pediatric Regulation.
- 1000 Paediatric Investigation Plans but only 131 completed.
- Proportion of trials in paeds ↑ from 8.25% to 12.4%.

Participación FH en EC pediátricos



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Tipos investigación pediátrica

Ensayos industria

- Comercialización
- Procesos
- Documentación
- Instrucciones de manejo de fármaco

Procesos estandarizados
Disponibilidad local fármacos, material fungible
Reclutamiento
Periodos ventana si farmacocinética

Ensayos independientes

- Necesidad terapéutica no cubierta
- Investigador/ grupo independiente
- Protocolo

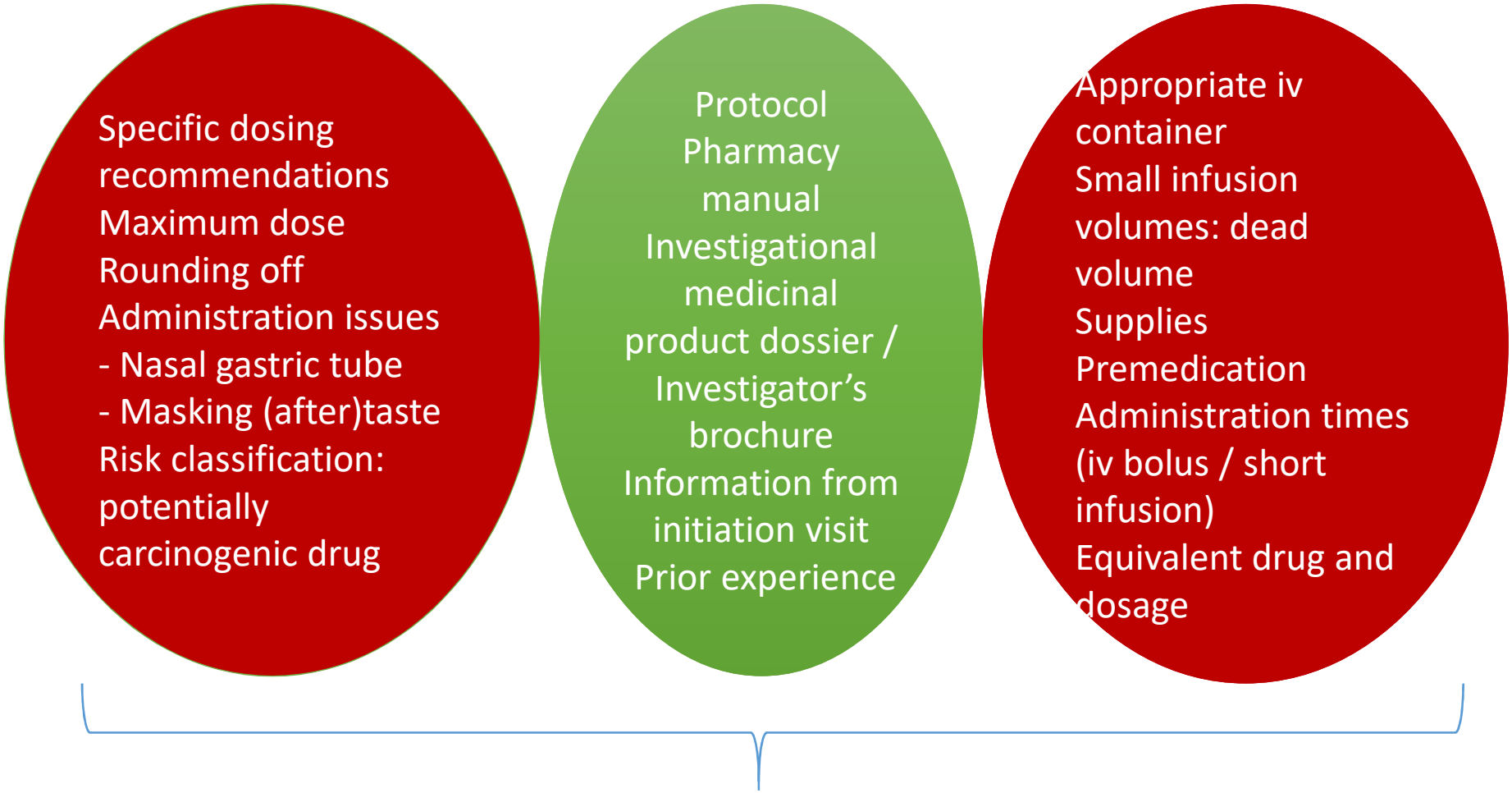
Menor especificación logística:
RESPONSABILIDAD
Disponibilidad fármacos multicéntricos
Fuera indicación
Formulación

Volumen administración

Dosificación según peso

Formulación según edad

Uso fuera de ficha técnica



Información necesaria EECC pediatria
Responabilidad preparación y administración segura

Evaluación del riesgo de fármacos en pediatría

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ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
Burlo Garofolo di Trieste

Safety knowledge

3. THE ESSENTIAL ROLE OF SAFETY MONITORING IN THE LIFE-CYCLE OF A MEDICINE

The benefit-risk assessment of any kind of medicine treatment is essential. No assessment of the treatment is, however, possible without safety data and knowledge. The "trial and error" principle is not acceptable in an extremely vulnerable population.

http://www.who.int/medicines/publications/essentialmedicines/Promotion_safe_med_childrens.pdf

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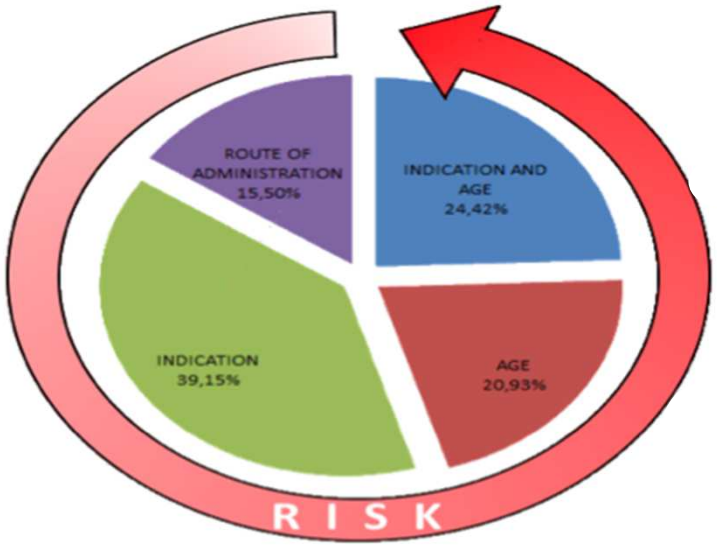
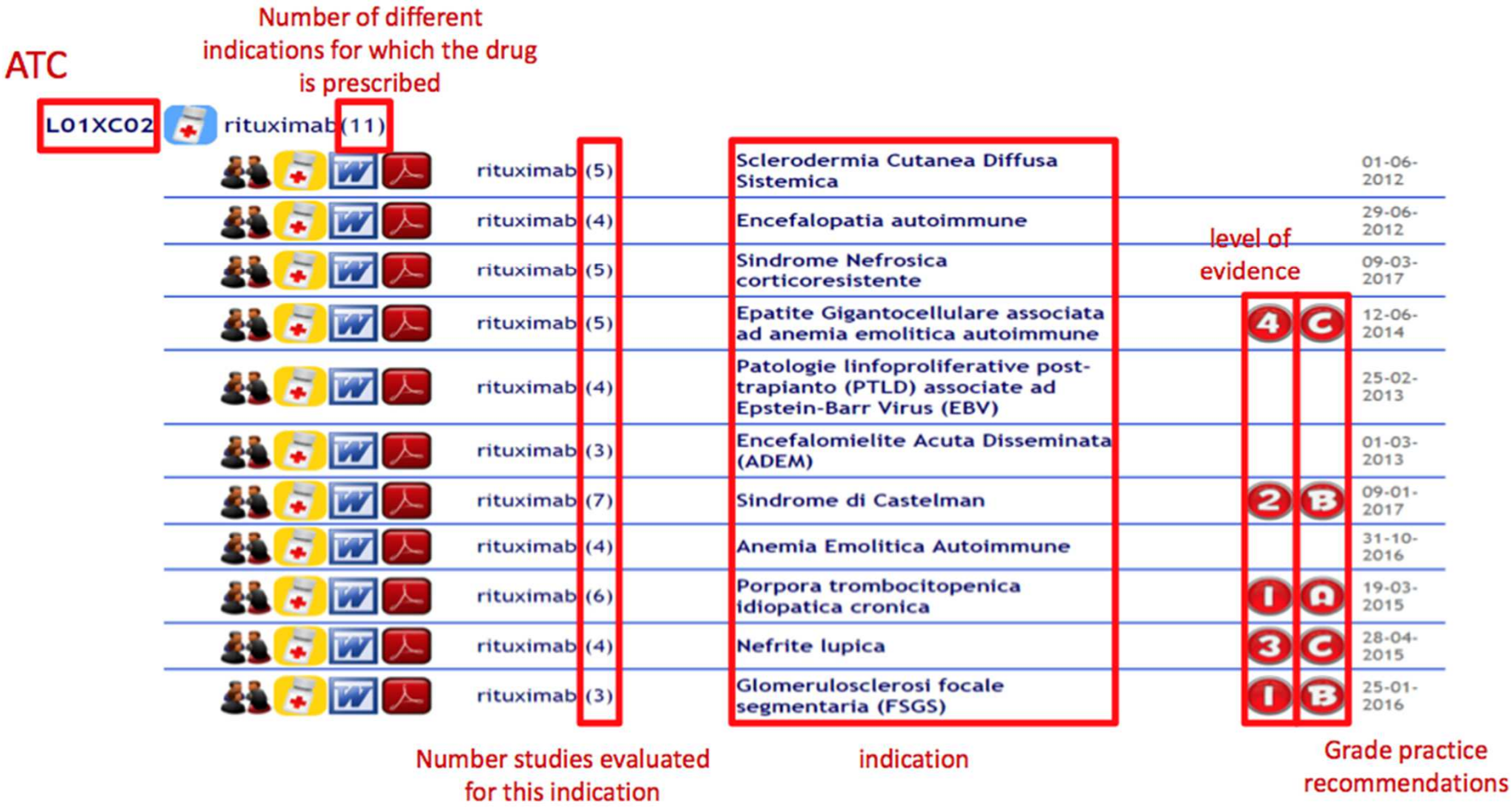
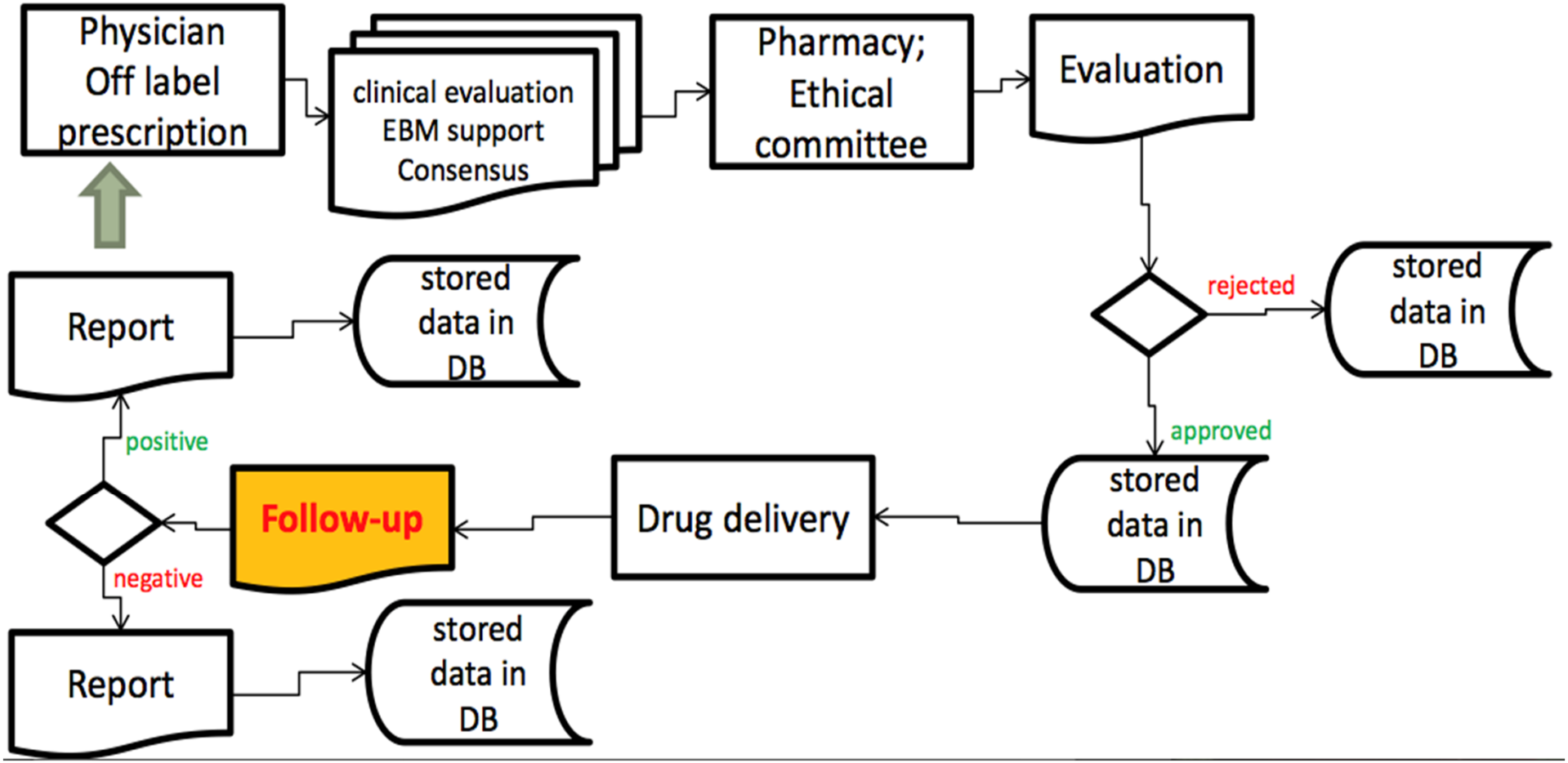
Uso fuera de indicación



- Age: Drug not recommended in the SmPC below a certain age
- Weight:Drug not recommended in the SmPC for children below a certain weight
- Absence of Paediatric Information: No mention at all in the SmPC regarding paediatric use
- Lack of paediatric clinical data: Stated lack of evidence of efficacy and safety in paediatric patients in the SmPC
- Contraindication:Statement in the SmPC that the drug is contraindicated in children
- Indication:Drug prescribed for indications outside of those listed in the SmPC
- Route of Administration:Drug administered by a route not described in the SmPC

Base de datos fuera indicación




Physician
Off label
prescription
clinical evaluation
EBM support
Consensus
Pharmacy;
Ethical
committee
Evaluation
rejected
stored
data in
DB
approved
stored
data in
DB
Drug delivery
Follow-up
positive
negative
Report
stored
data in
DB
Report
stored
data in
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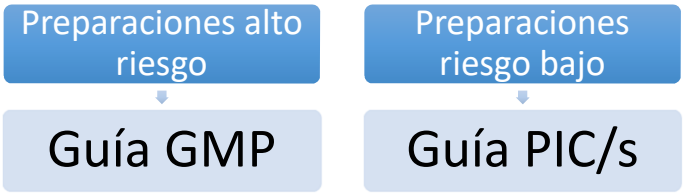
Riesgos asociados a la formulacion	
Unstandardised formulations	Organoleptic issues
Calculation errors	Measurement & labelling errors
Formulation failure (OD or UD)	Toxicity & contamination of raw materials
Uniformity of dose	Bioavailability issues
Binding of drug to excipients	Safety & efficacy untested
Micro contamination	QA/GMP issues
Staff issues	Use of concentrated raw materials e.g. concentrated chloroform water

1. Conocer a tu paciente
2. Comentar el caso con su médico
3. Evaluar el riesgo de la preparación
4. Preparar la mejor formulación pero sin permitir que afecte a la estabilidad
5. Asegurar uso seguro en casa

Resolution CM/Res(2016)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients

All pharmacy-prepared medicinal products should be prepared using an appropriate
- quality assurance system.
- risk assessment before preparation



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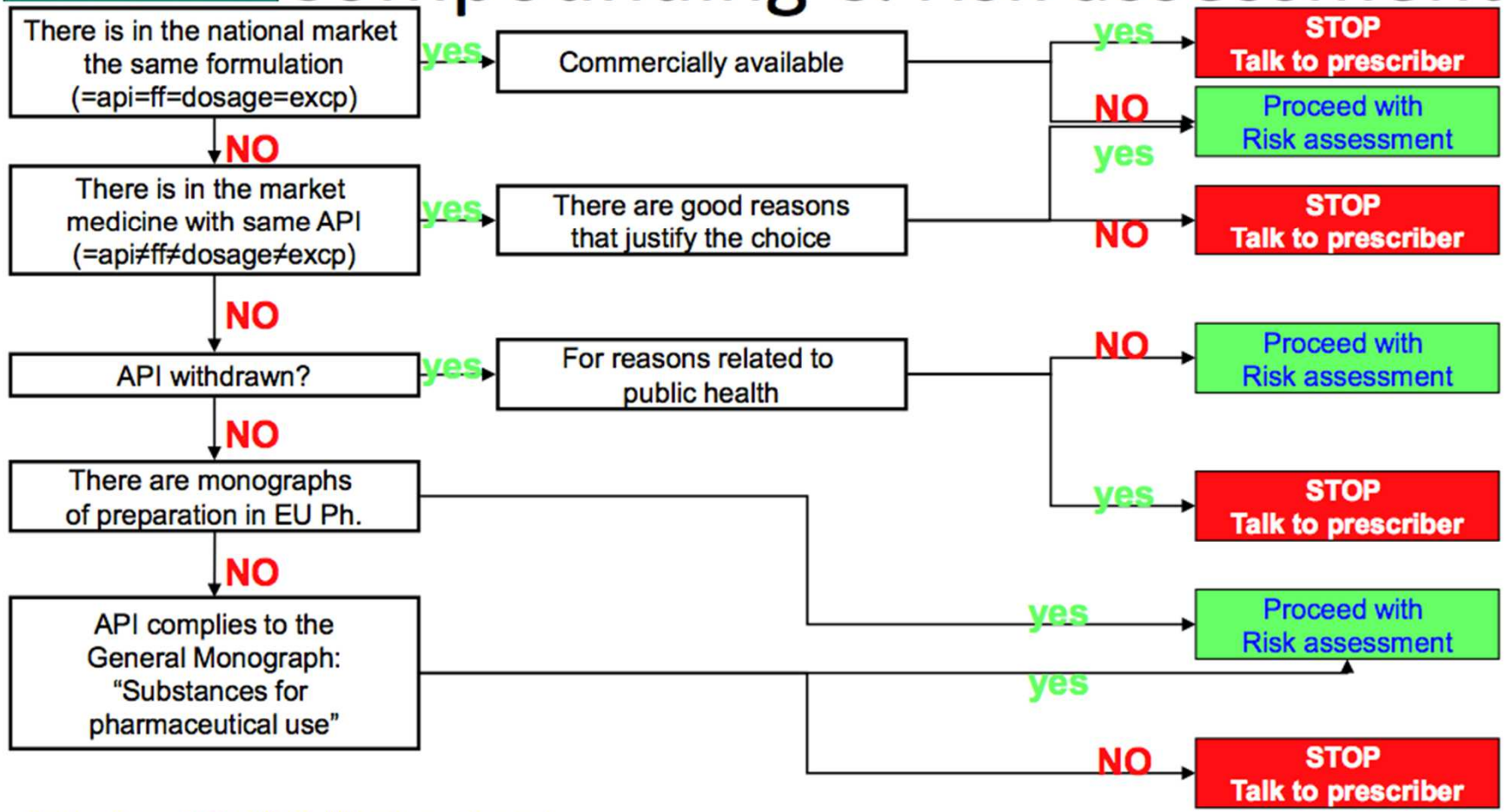
Compounding & risk assessment



Position Paper SIFO-SIFAP - https://www.sifap.org/

Table 3 Excipients known to be harmful and potentially harmful to neonates used in study population, their applications and safety concerns

Excipient	Functional category†	Applications and typical concentration	Safety concern

Table 4 Most commonly prescribed medicines (received by >10 patients) containing known to be harmful or potentially harmful excipients

Rank	Active substance, drug formulation	No of prescriptions	Potentially harmful or known to be harmful excipients
1	Gentamicin, inj solution	200	Parabens, sodium metabisulphite
2	Simeticone, oral suspension	108	Sodium benzoate, saccharin sodium, silicium dioxide, sodium cyclamate, sorbic acid
3	Heparin, inj solution	86	Benzyl alcohol, parabens
4	Laurilsulphate + Sorbitol + Sodium citrate, rectal solution	60	Sorbic acid

Table 2. Excipients effect in cytochrome P450.

Excipient	CYP3A	CYP3A4	CYP3A5	CYP2C9	Glucuronidation
Kolliphor® HS15	+				+
Kolliphor® EL	+	+		+	+
Kolliphor® RH40		+		+	+
Tween-20®	+		+		+
Tween-80®	+	+	+	+	+
PEG400	+				+
PEG1000			+	+	
PEG3350	+				
Myrj® 52	±	+		+	
Brij® 35		+			
Poloxamer 188	±	+	+	+	
Poloxamer 235	+				
Poloxamer 403	–				
Poloxamer 407	–				
Vitamin E TPGS	–	+			
Thiomers		+			
Modified cyclodextrins		+		↑	
Sucrose laurate		+		+	
HPMC	+				
Croscarmelose sodium	+				
Sodium starch glycolate	+				
Silicon dioxide	+				
Magnesium stearate	+				
Dicalcium phosphate	+				
Crospovidone	+				
Propylene glycol	+				
Acetic acid	+				
Malic Acid	+				
Triacetin	↑				
Phtalates	↑				
Lactose	–				
Cellulose microcrystalline	–				
Povidone	–				
Sodium starch glycolate	–				
Sodium lauryl sulfate	–				
Sucrose	–				
Cetyltrimethylammonium bromide	+				

(+) inhibition; (–) no inhibition; (±) variable information (↑) enzymatic induction.
HPMC: Hydroxypropyl methylcellulose; TPGS: Tocopherol polyethylene glycol succinate.

Table 3. Excipients effect on transporters.

Excipient	P-gp	MRP2	BCRP	OATP
Kolliphor® HS15				+
Kolliphor® EL	+	±	+	+
Kolliphor® RH40	±	+	–	
Tween-20®	+			
Tween-80®	±	+	+	
PEG400	+	+	–	+
PEG300	+			
PEG2000		+		
Myrj® 52	+		–	
Brij® 35	+			
Brij® 30			+	
Span® 20	+		+	
Span® 40	–		–	
Span® 80	–		–	
Poloxamer 181	+			
Poloxamer 188	±	–		
Poloxamer 235	+	+	+	
Poloxamer 333	+	–		
Poloxamer 403	+			
Poloxamer 407	+	±		
Vitamin E TPGS	+	+	–	
Sodium lauryl sulfate		+		
Transcutol®		+		
Sucrose laurate	+	–		
Labrasol®	+	±		
Gelucire® 44/14	+		–	
Stearyl ether	+			
Softigen® 767	+			
8:0 phosphocholine	+			
10:0 phosphocholine	+			
cis-22:6 phosphocholin	+			
Propylene glycol	–		–	
Ethyl oleate	–		–	
Triacetin	–		–	
Inwitor 742®	+			
Miglyol®	+			

(+) inhibition; (–) no inhibition; (±) variable information.
BCRP: Breast cancer resistance protein; MRP2: Multidrug resistance associated protein 2; OATP: Organic anion transporting polypeptide; P-gp: P-glycoprotein.

The biopharmaceutical classification system of excipients,Teófilo Vasconcelos, Sara Marques, Bruno Sarmento,Ther. Deliv. (2017) (2), 65–7

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Tack så mycket
Muchas gracias