Federal agency for medicines and health products

Implementation of the Clinical Trial Regulation in Belgium

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20 th of May, 2015

Agenda

- Overview
- Steering Committee for the implementation of the CTR in Belgium
- Main projects
- Focus on early phase

Commitment of the Belgian new Government

"In verband met de klinische proeven zal de deskundigheid van het Federaal agentschap voor geneesmiddelen en gezondheidsproducten (FAGG) worden versterkt voor een snelle evaluatie en goedkeuring van aanvragen voor klinische studies. Er zullen vereenvoudigde systemen worden ingevoerd voor een gecoördineerde evaluatie door het FAGG en de ethische comités en het werven van patiënten zal worden vergemakkelijkt "

- **Strenghten the expertise at famhp in view of respecting the strict timelines and a fast evaluation**
- **Coordinated evaluation between famhp and ethics committees (lean management , IT project)**
- **Facilitating the enrollment of patients in clinical trials**

CT Regulation : Critical issues

Thema's	Stakeholders													
	Politiek		Ethische Comités	Ziekenhuis directeurs	Hospitaal Apothekers	Patient Citizen	Commerciële sponsors (pharma,be, CRO's,	Academics	FAGG internal					
	NAT	EC/EMA							R&D	Evaluatoren	IUS	Inspectie	IT	andere
Werkproces + IT EU Portal	++	+/-	++	+		++	++	++	++	++	+	+	++	COMM
National contact point CTAG vertegenwoordiging	++		+				+	+	++		+			
Fees	++		++	+			++	EP++	++	++		++	++	B&BC
Safety	+		+			+	++	++	++	+				POST
Transparancy		++				+	++	++	+/-		++			
National criticalities	++		+/-				+	+	+		++	+		MLM
Changes in national legislation	++		+/-				+	+	+		++	+		
National indemnisation	++		+/-	++			+	+	++		+			
GXP requirements inspectie related	+	+	-	++	++		+	++	-	+/-		EP++		Inspectie
QA	+	++	+						++	++	++	++	+	kwaliteit

Steering Committee

Mandate :

- **Design , adoption and surveillance of the workplan for the implementation of the CT Regulation at national level**

- **Aligned with the discussions at the level of the EU CTR umbrella, European Commission, EMA (EU Portal) , HMA's CTFG**

Steering Committee

Composition :

- **Political responsables (at national level)**
- **Ethics Committees**
- **Hospital directions**
- **Hospital pharmacists**
- **Patient organisations**
- **Commercial sponsors**
- **Academic sponsors *(investigators ?)***
- **Famhp**

Main Projects (1)

- **Set up the workprocess for decision making and surveillance of CTA's :**
  - **Model of collaboration between EC's and famhp**
  - **Assessment process within EC / famhp**
  - **Link with EU portal group**
  - **National IT systems needed**
  - **Selection criteria for RMS**
  - **« Contracts » part of the workprocessflow ?**
- **Stakeholders involved : Ethics committees, Patient representatives , Sponsors (commercial and academic) , famhp**

Main Projects (2)

- **Determine the GXP requirements :**
  - **GCP & GMP**
  - **Radiopharmaceuticals**
  - **Magistral / officinal preparations**

- **Priority for European Commission : Ad Hoc Group 9 th March 2015**

- **Stakeholders involved : Hospitals (direction + pharmacies), Sponsors (academic and commercial) and famhp**

Main Projects (3)

- **Establish the Belgian contact point and representation in the European platform CTAG**
- **Dependent on the decisions of collaboration model- transfer of information to be guaranteed**
- **Needs to be in place before the entry into force**

Main Projects (4)

- **Determine the fees**
- **Dependent on the decisions of collaboration model**
- **Only one fee per Memberstate (no separate fee for ECs / famhp /…) – activity based costing**
- **Needs to be in place before the entry into force**

Main Projects (5)

- **Determine the national criticalities :**
  - **Legal representative or contact person**
  - **Cluster trials**
  - **Minors in clinical trials**
- **Needs to be in place before the entry into force**
- **Key decision points for position of Belgium**

Main projects (6)

- **Update the national legislation where needed :**

- **Process of non-interventional studies ?**
- **Process for medical devices investigations ?**
- **…**

- **Stakeholders : all members of Steering Committee**

Main Projects (7)

- **Clarify the requirements on transparancy of clinical trial data**
- **Dependent on the discussions of the EU Portal**
- **Dependent on the evolutions of EMA's policy**

Main Projects (8)

- **Investigate the feasibility of a national indemnisation system**

- **Not an obligation, but already in place in some EU countries (DE, DK) – under investigation in NL, FR,…**

Main Projects (9)

- **Safety surveillance : worksharing of the assessment of safety signals**
- **Under development at the EU level**
- **Implementing act possible**

Main Projects (10)

- **Quality assurance of the system in light of the audits by the European Commission**

Workplan

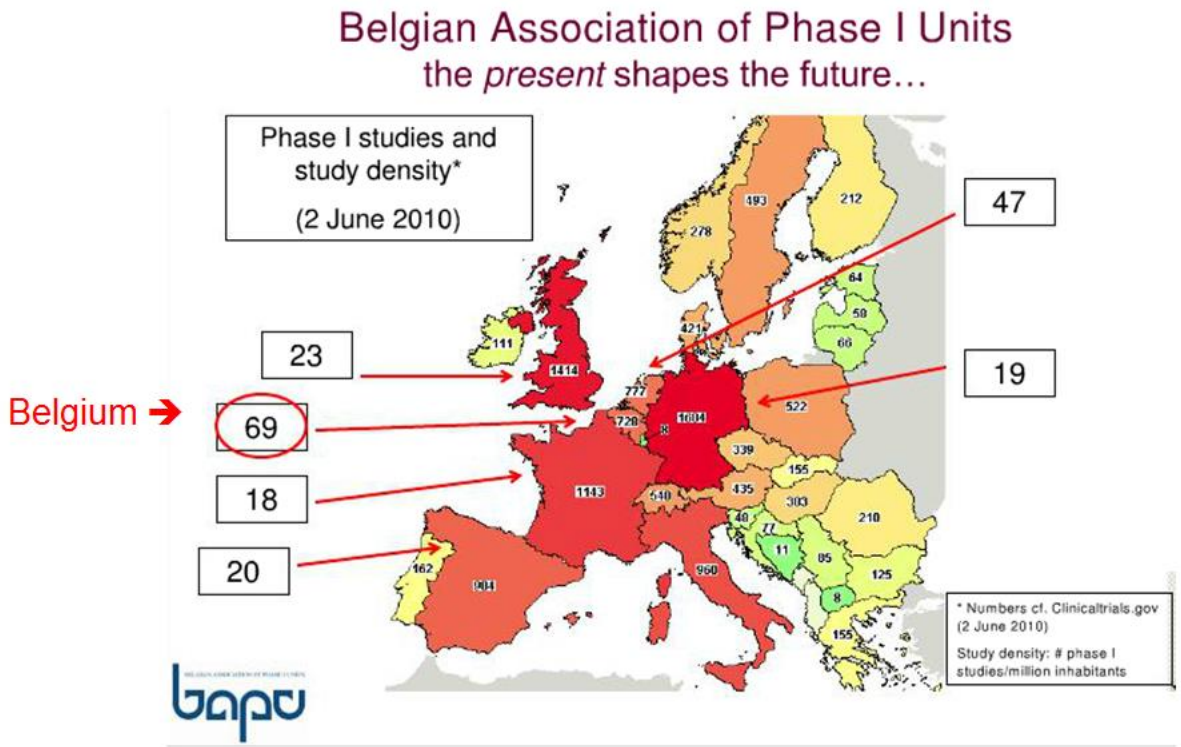
Focus	Objectieven	Verantwoordelijke	Leden	Tijdslijn
Design WorkProcesFlow	Formeel voorstel van de workflow en de IT-support: - samenwerkingsvoorstel EC's - fagg - scope (contracten pro-contra) - evaluatie proces: EC - fagg - IT-impact (EU portal, intractieve website Ecs) - selectiecriteria RMS (commercial - non commercial)	Kristof Bonnarens	ECs Patiënten representatie Sponsors R&D Assessoren IT	Q2 2015 Pre-inception IT start Q2 2015
Bepalen van GXP vereisten	Voorstel herziening GCP/GMP directive: - input herziening GCP/GMP directive - nationale positionering tov magistrale bereidingen, radiofarmaca, ATMPs,…	Karine Froidbise Walter Janssens	Hosp-Dir / Hosp-Aprs Sponsors fagg	ongoing
Retributie (fee)	afspraken mbt methodologie	Greet Musch Pascal Giloteau		Q3-4 2015
Nationale kritische zaken	Beleidsopties definiëren voor de geïdentificeerde kritische items (minors in CT, legal representative, cluster trials)	Kristof Bonnarens Steering Committee Els Vermeulen		ongoing
Herziening Wet 7 Mei 2014	Nieuw Wetsontwerp klaar Plan van Aanpak Methodologie & Tijdslijn GAP analyse: wet versus regulation: Kritische issues: - nationale kritische zaken - verder definiëring van de consultatie van de verschillende sectoren (voornamelijk academische sector)	Els Vermeulen Steering Committee		end of 2015 sept 2014 sept 2014
Transparency	Opstarten discussie	Greet Musch Steering Commitee		ongoing
National indemnisation system	Opstarten discussie: voorbereiding pro/contra tov bestaande modellen in andere lidstaten	Katelijne De Nys EFGCP Greet Musch		Q2 2015
Safety Surveillance	Worksharing	Kristof Bonnarens Caroline Van Droogenbroeck		Q3 2015
QA	Werkpklan ifv audits bij EC	Christelle Beeckmans Greet Musch Steering Committee		action plan early 2016

Current priorities at Belgian level

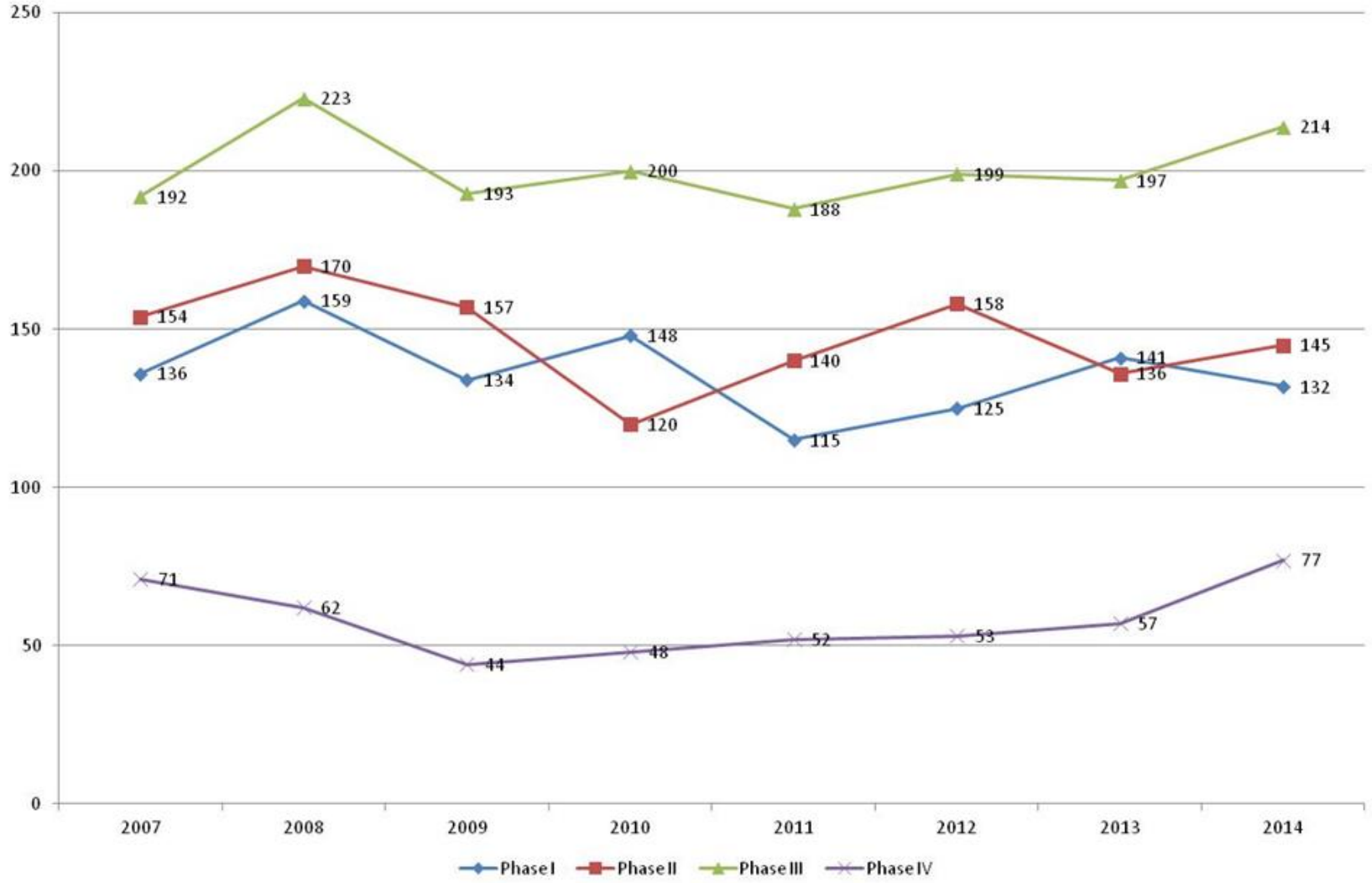
- **Workprocessflow, IT support inclusive assuring adequate assessment according to the highest scientific standards , within the legal delays (short for phase 1 trials) in a cost effective way**
- **Harmonisation of ethical issues related to clinical trials**
- **Fees : ABC methodology ; attention for academic trials**
- **Law 7 may 2004 revisited**
- **Reflection paper on facilitated recruitment of participants/patients into clinical trials**
- **Imbedding into the life cycle of drug development (Therapeutic Area Coordination)**

Early phase trials

- **DATA from BAPU**



Comparison of CTA in different phases



Belgium: future developments

- **FAMHP focus point = Enabling Early Phase Research**
- **Short timelines for evaluation of clinical trials and in particular of early phase clinical trials max. 15 calendar days and often faster**
- **Strong commitment of the FAMHP to maintain short timelines also after coming into force of the Regulation on clinical trials**
- **On site formulation**
- **Willing to introduce « certification » of early phase units**

Belgium: future developments

- Focus on early phase, oncology and vaccines
- Facilitating fast recruitement (healthy volunteers and patients) aligned with centres of excellence at national and EU level
- Accessible / interactions
  - Agency working groups with stakeholders on important issues
  - Agency system of scientific advice: short timelines and in particular for focused written advice (one question)
  - Iterative processes are possible

Thank you for your attention !

Your medicines and health products, our concern

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