INSTITUT
JULES BORDET
Clinical Trials Support Unit

CTR Pilot :
Experience of Institut Jules Bordet.
23/09/2021.

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ULB iris

Institut Jules Bordet

- Based in Brussels.
- Integrated, multidisciplinary centre, devoted entirely to patients affected by Cancer.
- Participation in cancer research by running clinical studies designed by its researchers (sponsor) and by other research groups and pharmaceutical companies across the world.

Clinical Trials Support Unit (CTSU)

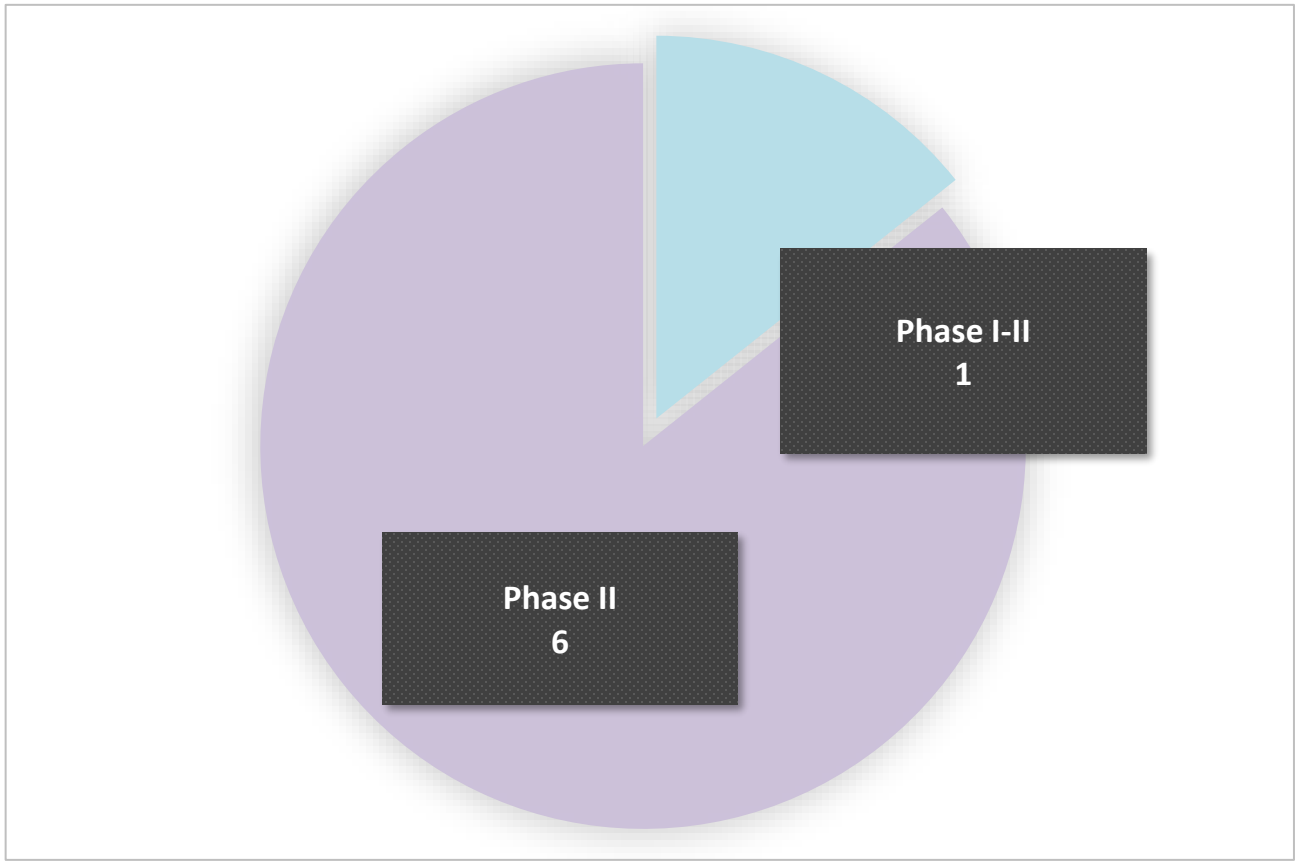
- Department of Institut Jules Bordet that assist researchers of the academic and industrial worlds in the development and conduct of clinical studies

- Experience of more than 20 years, a wide range of activities and services : Clinical study management, Regulatory Affairs, Pharmacovigilance, Sites Monitoring….

https://www.bordet.be/en/clinical-trials-support-unit-ctsu

CTR pilot : our experience at the CTSU

Since October 2018, 7 our of clinical trials are run under the CTR pilot of the EU regulation :



Trials parameters

Trial #	*International*	*Number of sites in BELGIUM (initial submission)*
1	YES	3
2	YES	10
3	YES	1
4	YES	6
5	NO	9
6	YES	3
7	YES	10

All our trials are multi-centers.
6/7 are run abroad.

Trials parameters – Initial Submissions

Trial #	*Initial Submission Approval*	*Number of days from submission date to authorisation date*
1	2018	66
2	2018	43
3	2019	52
4	2020	53
5	2021	134*
6	Submitted on 05/08/2021	UK*
7	2021	100*

4/6 authorisations were given within the expected timelines.

Trials parameters – Substantial amendments

Trial #	*Number of substantial amendments*	*Assessment in days : min-max*	*Average in days*
1	6	17-52	35,5
2	6	21-62	36,5
3	2	49-50	49,5
4	2	35-65	50
5	0	/	/
6	0	/	/
7	0	/	/

The timelines of assessment of the substantial amendments were within the expected timelines.

Impacts on the timelines

Longer timelines

Waves of COVID

Multi-topics amendments (protocol, ICF, IMPD...)

Shorter timelines

Addition of a new site or site closure

Reference Safety Information

Pros and cons of the CTR pilot

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- Platform (CESP)
- Guidelines
- Structure of the dossiers (initial, SA) and templates
- Simplified submission for multicentric trials (e.g. no internal documents for all LECs, no coordinated submission EC/LEC/AFMPS)
- No intention letter anymore at one point
- Consolidated RFI

(-)

- Booking of slots
- Heterogeneity of RFI (i.e. EC : wording while using the national template of the ICF or wording from an ICF approved by another EC)
- Comments on documents that are not own by IJB (e.g. investigator's brochures) whereas timelines are very short to reply to a RFI
- Requirements which hinder the international submission (e.g. naming of the documents, templates)

Conclusion

Thanks to the CTR pilot phase, we have :

- gain experience
- templates and processes in place

which can be easily applied once the regulation is effective.

Acknowledgements

- AFMPS for the invitation

- Availability of AFMPS colleagues and their willingness to help us (e.g. trial 7)

LAST MESSAGE….

We are moving!

When? End of November 2021

Where? Rue Meylemeersch 90, 1070 Anderlecht

More info on www.bordet.be/en/bordet-new