



Harmonize your UK and EU CTA submissions: Practical strategies from EU-CTR experience

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Our agenda today

Discussion topics

European regulatory landscape

New MHRA regulatory guidelines

Effective EU&UK submissions strategies for sponsors

Proactive solutions on common CTA submissions challenges

Key takeaways and lessons learned

Q&A



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Turning post-Brexit regulatory complexity into advantage

- › Picture January 2020: Brexit arrives, and the UK begins running independently from the EU regulatory framework. Two separate systems emerge, yet **many scientific and ethical principles stay aligned—a bridge for smart sponsors.**



- › **Here's the opportunity:** a **harmonized strategy** minimizes redundant work in preparing separate dossiers, while **parallel or coordinated submissions** accelerate overall approval timelines. Why does this matter? Because **UK and EU markets remain critical for drug development**, and **multi-country trials** are essential for adequate patient recruitment.



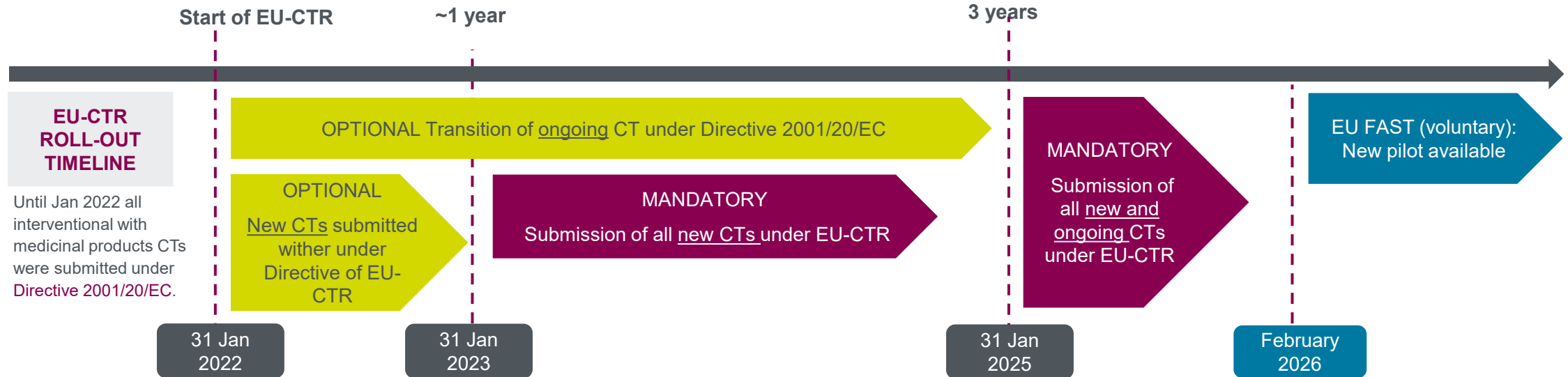
The payoff? A harmonized approach **facilitates marketing authorization applications in both regions**, turning regulatory complexity into **strategic advantage**. Smart planning today means faster patient access tomorrow.



European and UK's regulatory landscape for CTAs

Understand the requirements, and use the opportunities

Evolution of EU regulatory landscape over the years



EU Clinical Trials Regulation (EU-CTR) 536/2014 became applicable to **interventional phase I to IV trials** as of 31st January 2022

One **EEA submission** with synchronized member state-level decisions across the European Economic Area (EEA; 30 countries: EU plus Norway, Iceland, Liechtenstein)

All submissions and communication only **electronically** through the EMA CTIS (Clinical Trial Information System), with Ethic Committee submission **integrated** into CTIS

What needs to be done for EU-CTR compliance



Application submission

RFI* response: Use advantage of stringent amendment process, four slots per year on average, with every package reviewed in its entirety.



CTIS operating model

CTIS management: Assign proper operational user model and task management (roles and permissions). It is a powerful tool, but requires preparation, attention to detail, and strategic navigation. Make sure to watch the portal and capture any request to be addressed in due time.



Transparency

Selected approved trial **EU-CTR documentation and information** to become **publicly** available:
Establish process for **redaction due to transparency rules and local registries**.



Master databases

Data management: Ensure all your products and organizations are available in EMA Master Databases as prerequisite for submission.
Maintenance of CTIS source information in EMA source Master Databases (xEVMPD, OMS, RMS) is also required.

*RFI - request for information; max 10 calendar days for validation RFI and max 12 calendar days for assessment RFI response, otherwise application lapses

How to benefit from FAST-EU Pilot for EU-CTR submissions

- EU Clinical Trials FAST-EU is a voluntary, 1-year pilot under the EU-CTR designed to **accelerate authorization of multinational clinical trials** with target timeline of **70* calendar days** until conclusion, applicable as initial multinational CTA submission for all IMP categories**

Selection rules

- ~2 trials/month
- Trials prioritized by:
 - High number of MSCs
 - Dossier readiness
 - Scientific/clinical relevance
 - Prior EMA engagement & RMS availability
- Eligibility not guaranteed; alternative slot or RMS may be assigned

Requirements

- Expression of Interest (Letter of Intention, Lol) required before CTA submission
 - Dossier must be finalized prior to Lol and ready for submission within 2 working days of acceptance
- Only one RFI round (Part I and Part II)
 - Insufficient responses may lead to conditions or rejection
- Conditional approvals may require additional substantial modifications

Key improvements



Full integration of ethics and regulatory assessment



Significant reduction in end-to-end timelines via parallel workflows



Streamlined processes with single-round RFIs requiring consolidated responses

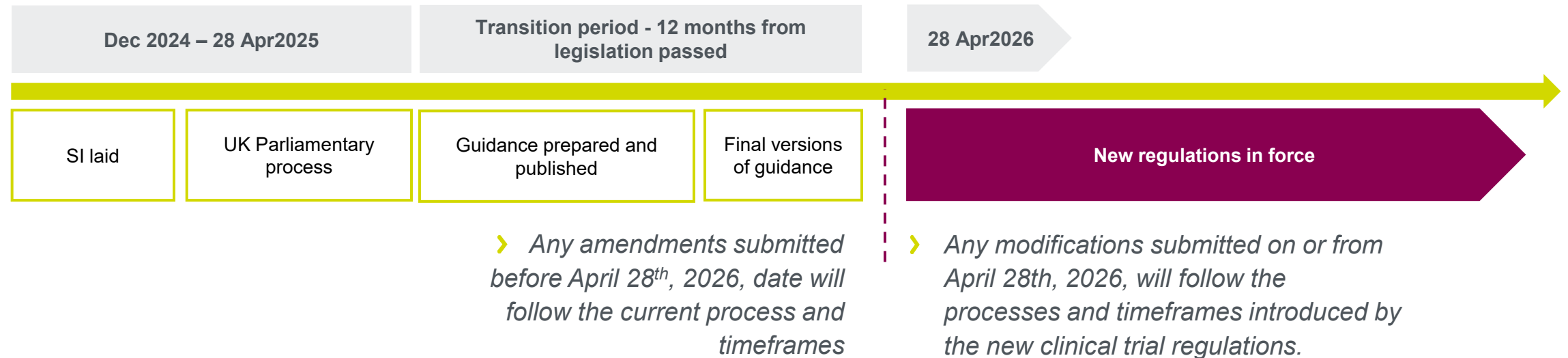
*from submission to conclusion across all MSCs, including sponsor responses

**excluding mono-national trials, partial submissions, resubmissions, substantial modifications

The new CT regulations in the UK

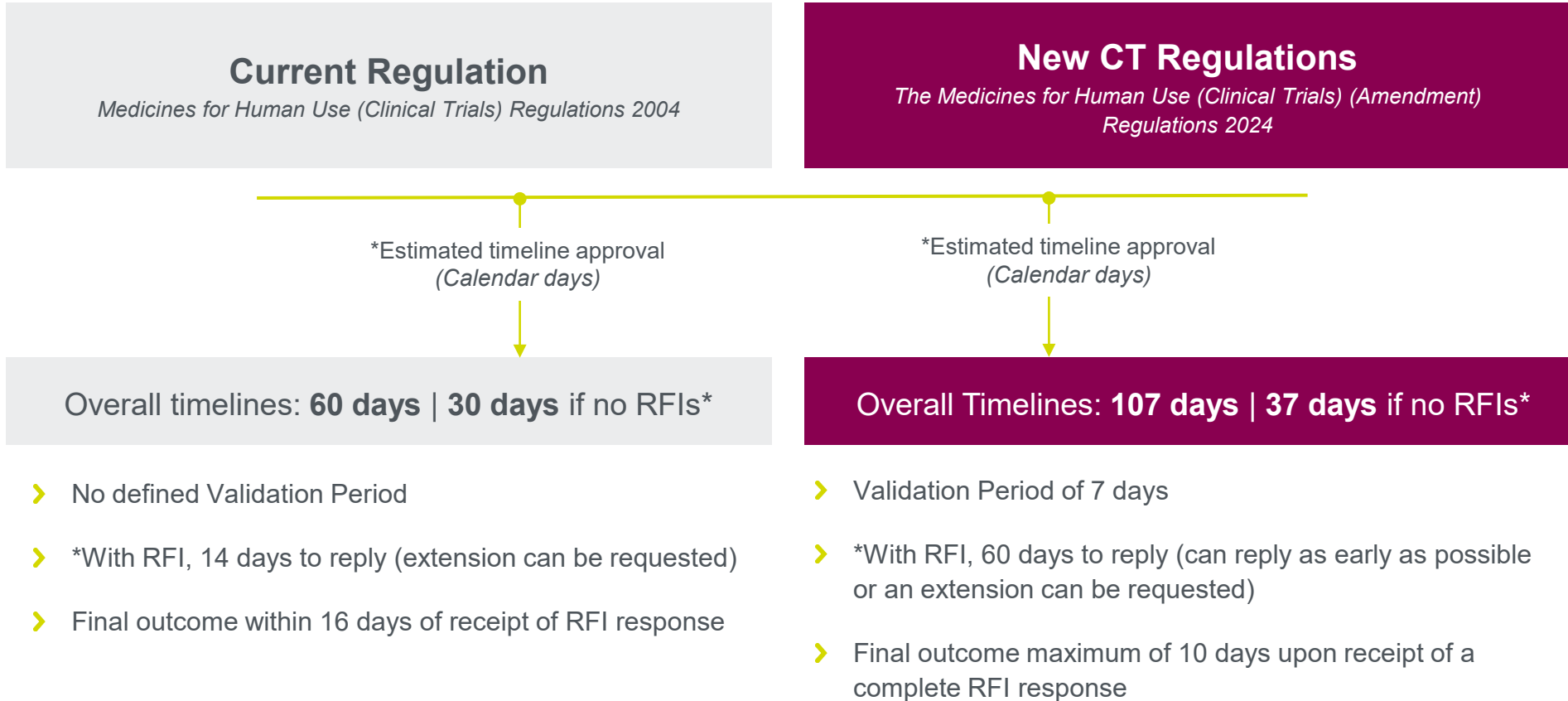
Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024

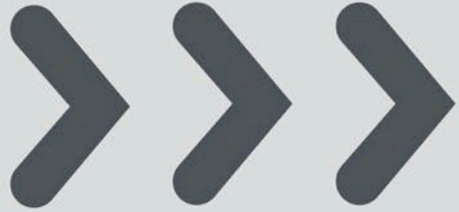
New Clinical Trials Regulations was developed by the Medicines and Healthcare Products Regulatory Agency (MHRA), in partnership with the Health Research Authority (HRA), and shaped by feedback from patients, researchers, doctors.



Main changes in the UK regulatory framework

How sponsors can benefit from the extended RFI timelines





Capitalizing on the UK and EU clinical trials submission opportunities

Techniques for harmonizing and streamlining CTA
submissions across UK and EU regulatory frameworks

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Comparison of clinical trials regulatory framework

MHRA and EMA solutions



Key aspects	UK (MHRA)	EU (EU-CTR)
Portal	IRAS/MHRA portal	CTIS (Clinical Trials Information System)
Timeline	Typically, faster	Standardized timelines
Assessment	National	Coordinated (MSC/CMS model)
Transparency	Moderate	High (public portal)
Flexibility	Increasing post-Brexit	Harmonized approach
Scientific Advice	MHRA Innovation Office	EMA Scientific Advice

Strategic planning to power MHRA opportunities

1

Engage early with *Innovation Office for Scientific Advice* on novel products and complex development programs

2

Utilize early access to *Medicines Scheme (EAMS)* for addressing unmet needs

3

Take advantage of expedited pathways for breakthrough therapies

4

Assess applicability for *Notifiable Trials*: review eligibility criteria

5

Consider joint scientific advice meetings with MHRA and EMA for aligned development strategies

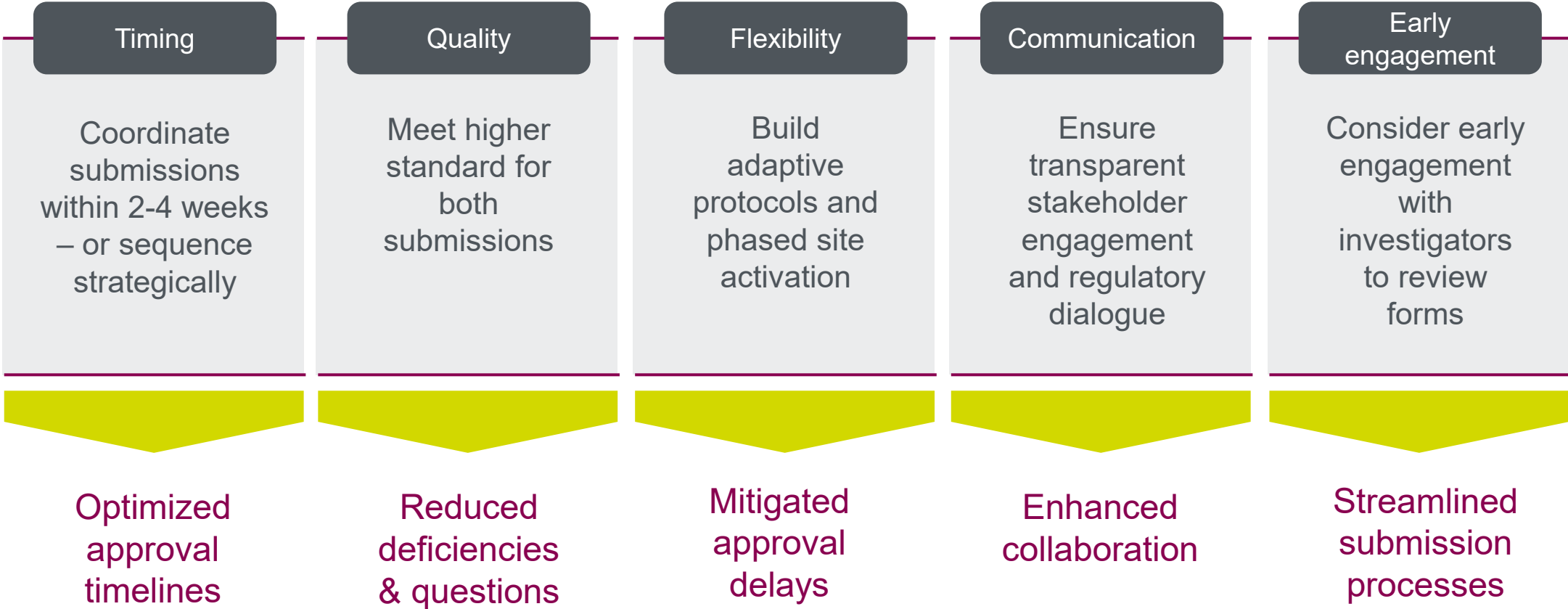
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Use MHRA approval as a steppingstone for broader European market access

- › Given the UK's streamlined site/local documentation requirements, consider pursuing a sequential submission strategy, initiating the **UK CTA ahead of the EU** submission to optimize timelines

Capitalizing on the MHRA and EU regulatory pathways

Recommended actions to maximize benefits





Common CTA challenges and proactive solutions

The strategic advantage of leveraging MHRA speed and flexibility

Why MHRA first? >>> Gain early regulatory feedback that shapes global strategy, and achieve higher quality submissions with fewer validation issues

Faster review timelines

MHRA: initial decisions in **~37 days**

EU-CTR Part I: **~45 days**

EU-CTR Part II: up to **90+ days** (varies by Member State)

Greater flexibility

- › MHRA known from science-based, flexible decision-making
- › Open to novel trial designs and adaptive approaches
- › Early scientific advice informs EU submission strategy

Cross-learning advantage

UK → EU
Use MHRA feedback to strengthen EU responses

EU → UK
Apply EU Part I assessments to UK amendments (faster UK amendment timelines)

Leveraging synergies in CTA documentation preparation

Core documents | Single preparation

DOCUMENT	SYNERGY LEVEL	TIME SAVINGS
Protocol	95-100% identical	Prepare once, use twice
Investigator's Brochure	100% identical	Full reuse
IMP Dossier (CTD format)	90-95% identical	Minor regional adaptations only
Statistical Analysis Plan	100% identical	Full reuse
Monitoring Plan	95% identical	Minor local procedure updates
Data Management Plan	100% identical	Full reuse

Maximizing efficiencies for regional adaptations in core documentation

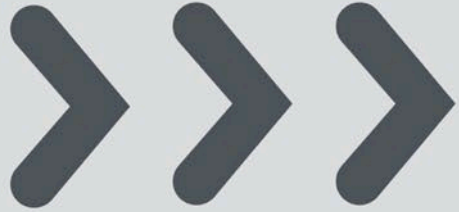
Master templates | Sequential submissions

Informed Consent Forms (ICF) and specific documents

- Core content 80% identical: adapt for specific requirements while keeping core content
 - UK-specific: HRA requirements, NHS patient information standards
 - EU: Member State-specific requirements
- **Time saving:** Develop master template for labels, then create regional versions (saves ~60% of time vs. separate development)

Regulatory Forms

- UK: IRAS (Integrated Research Application System) form
 - EU: CTIS portal submission
- **Efforts saving:** IRAS is comprehensive and CTIS can be completed with minimum additional information



**Enhance success rates and
reduce risks when navigating CTA
submissions in the UK and EU**

Aligned clinical trial submissions in the UK and EU

Situation

A pharmaceutical company initiated a Phase III interventional oncology trial across the UK and 8 EU countries. Seeking strategic regulatory advice and submission management, they partnered with Parexel to manage both planning and operations.

Challenges

Regulatory strategy development

Providing proper strategy for Clinical Trial Application procedures, requirements, and timelines tailored to the specific drug type

Country-specific intelligence

Collecting and analyzing regulatory intelligence on local regulatory environments across the UK and 8 EU countries

Solution >>> Offering a harmonized and combined regulatory submission for the UK and EU

- > Prioritized broader, and faster patient access with simultaneous UK and EU enrollment
- > Avoided duplication of effort to achieve faster timelines
- > Leveraged shared documentation and ensured data consistency to minimize protocol variations, and additional questions
- > Reduced risk of conflicting local requirements with relevant regulatory alignment, based on experience and Reg Intel outcome



Regulatory
expertise



Strategic
planning



Patient
access

Benefits

Patient impact: Accelerated patient access to innovative treatments saving 4-8 weeks to first patient enrolled

Maximized efficiency: Up to 40% reduction of resources and efforts

Streamlined approach: Harmonized UK and EU-CTA submissions to achieve faster timelines

Competitive advantage: Accelerated trial development

Best practices to optimize your CTA submissions in the EU, and UK

Strategic sequencing

- **Submit to MHRA first** for novel/complex trials to gain early feedback
- **Use MHRA approval** as credibility signal in EU submissions
- **Leverage MHRA's faster timelines** to accelerate UK site activation

Proactive engagement

- **Use MHRA Innovation Office** for early scientific advice that informs EU strategy
- Build anticipated **RFI response bank** before submission
- Implement **lessons learned process** to prevent future submission delays

Operational efficiency

- **Prepare core documents** once with 90%+ reuse between submissions
- **Establish unified response team** to handle RFIs efficiently
- **Monitor both portals* daily** with single point of contact

* CTIS and IRAS platforms

Key takeaways: **Experience, strategy, and expertise-driven automation drive faster patient access**



Patient access is accelerated through efficient regulatory strategies



Harmonization of the UK and EU submissions is achievable and beneficial



EU-CTR experience provides valuable lessons for dual submissions



Proactive planning and early alignment are critical



Developing **proficiency in technology*** supported by **regulatory expertise** generates tangible operational benefits

* CTIS and IRAS platforms

Questions?



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Harmonizing UK and EU CTA
submissions: Practical strategies from
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Thank you

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