NHS
Health Research Authority

Accelerating Clinical Development in the UK

Jonathan Montgomery
Chair, Health Research Authority

We aim, with partners, to make the UK a great place to do health research, to build confidence and participation in health research, and so improve the nation's health.

Objectives of the Health Research Authority

- Protect (potential) participants by encouraging research that is safe and ethical
- Promote the interests of those (potential) participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research)

Functions of HRA in Care Act 2014

- Co-ordination and standardisation of practice relating to the regulation of health and social care research:
  - Reduce duplication
  - Streamline
- Promote transparency in research
- Guidance – including replacement of RGF – NHS and local authorities must 'have regard'

The Health Research Authority

- Research Ethics Committees
- Transparency
- Research policy
- HRA Assessment and Approval plans
- Systems, including IRAS, TOPS and our research ethics database
- Advice, guidance, training, communications and engagement
- Public Involvement
- Confidentiality Advisory Group
- Collaboration and Development improvement projects

Why change?

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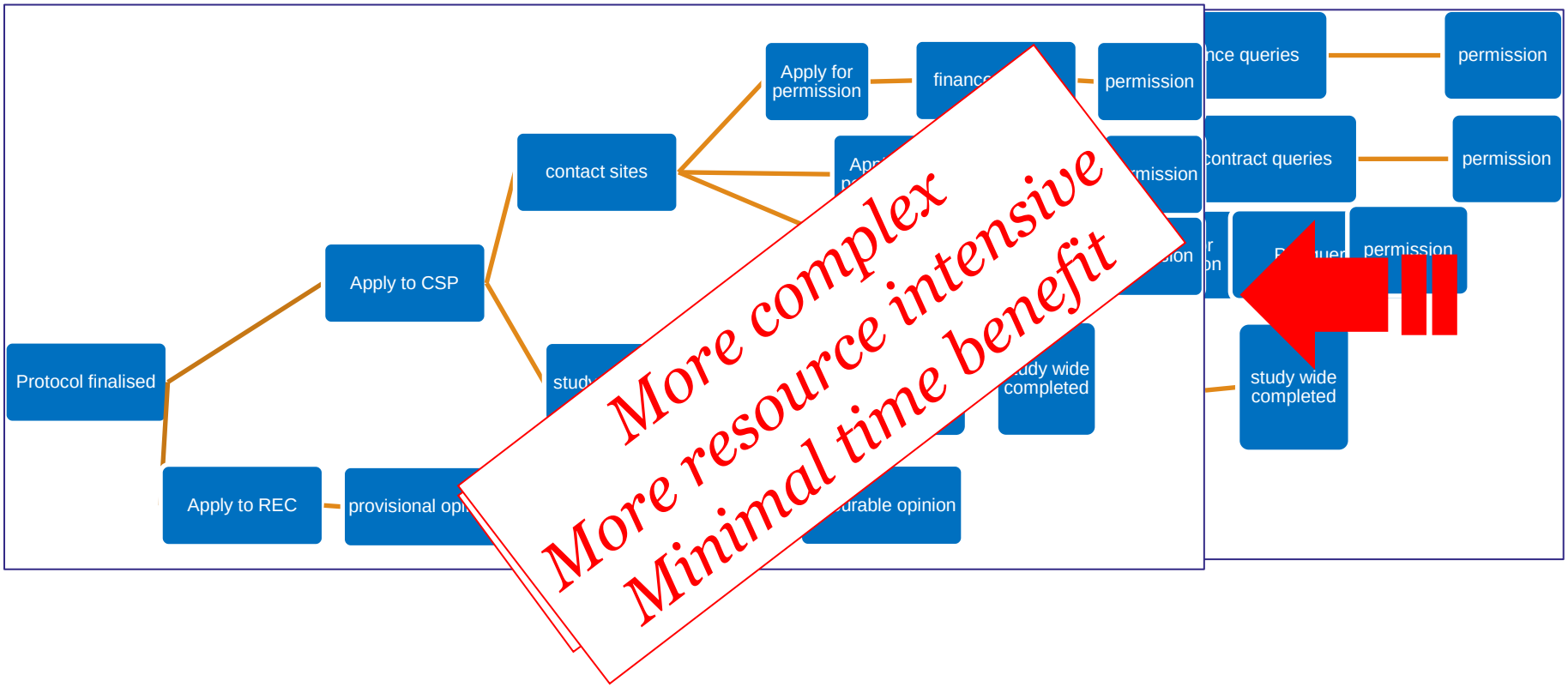

HRA Approval

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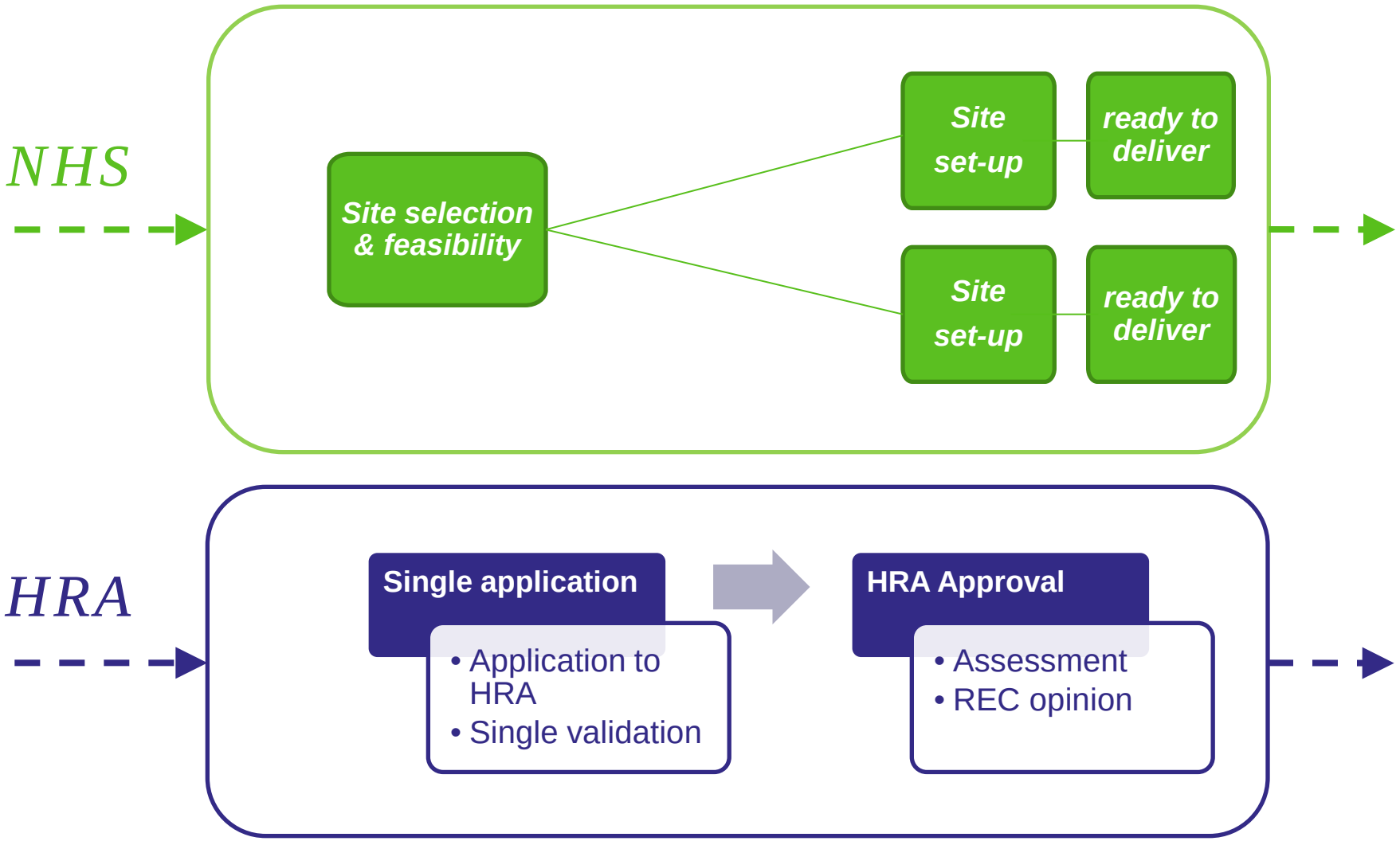

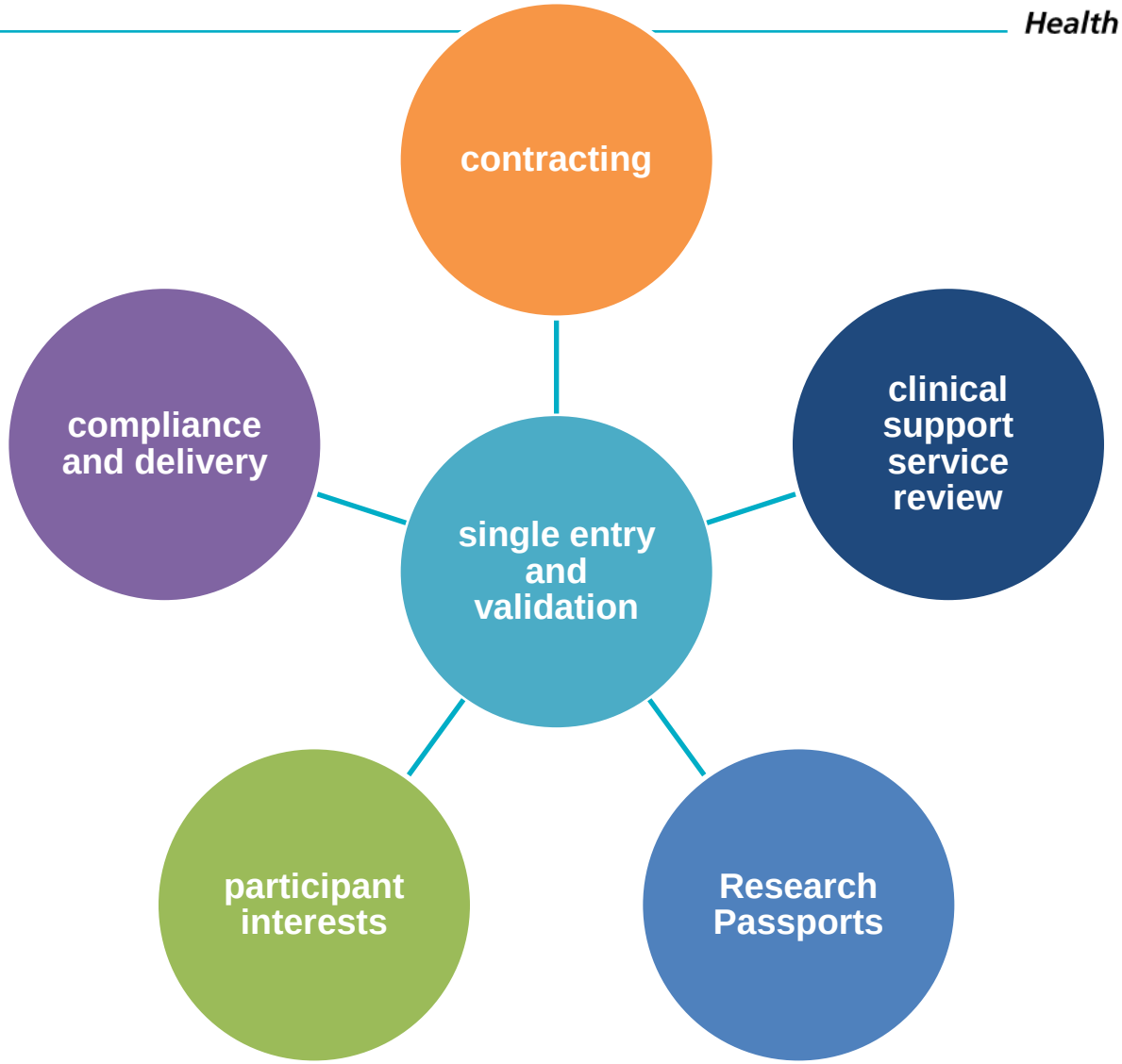
contracting
compliance and delivery
clinical support service review
single entry and validation
participant interests
Research Passports

Confirmation by HRA Assessors of appropriate contracts and agreements based on model templates

Assessment of compliance with legislation and arrangements for management in NHS

Validation of combined application against IRAS checklist by HRA validators

Centralised technical pharmacy and radiation review by accredited professionals to support NHS decision to participate

Judgement by HRA Assessors to improve quality and consistency of REC review

Judgement by HRA Assessors of appropriate Research Passport and HR arrangements

HRA Approval

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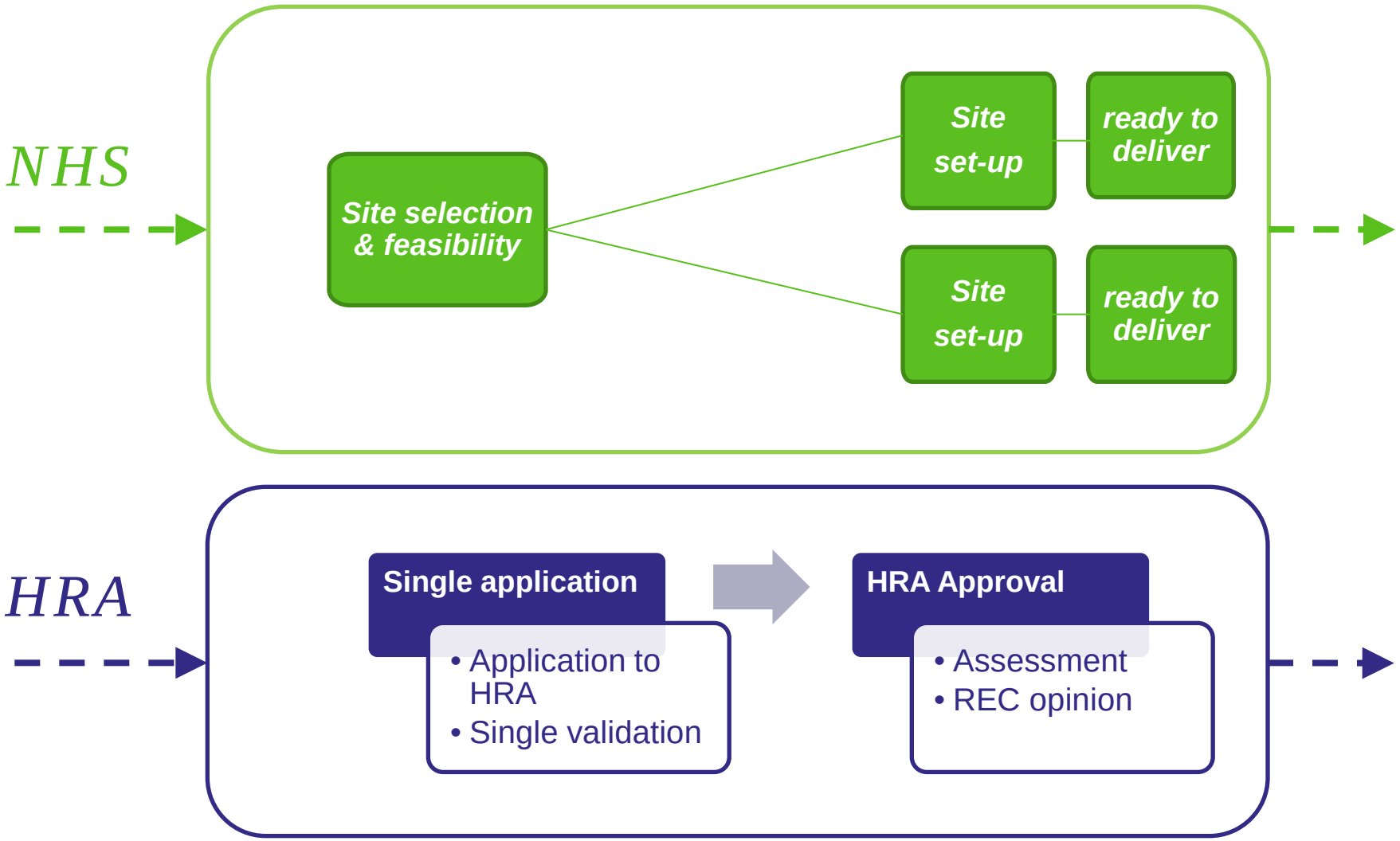

Site set-up and local decision to deliver

- Putting arrangements in place ready to start
- Local arrangements based on HRA assessment and Approval
- Local decision to participate and deliver (not local review or ‘permission’)
- Information exchange to get site ready for recruitment (based on approved protocol and documents)

PIC

Inappropriate HR checks

Local IG forms

Negotiation on contract terms

Local pharmacy technical review

Local radiation calculations

Action for NHS organisations now – HRA will support early readiness

Reduce variation

Improve interaction

Reduce waste and inefficiency

Focus on initiating and delivering research

Timetable and approach

- Now: Application management – rolling out pharmacy and radiation single technical reviews, supporting complex applications early through interim policies
- Now: Recruiting new staff
- Early: primary care, staff research, health services research
- By end 2015: all research

HRA Approval – key messages

- One application, one assessment and one approval for the NHS
- Phased roll out (no pilot sites)
- Roll out components – pharmacy / radiation
- Roll out proportionate approaches – rare diseases, cell therapy
- Roll out by study type – health services research, primary care
- Information systems to enable processes to be embedded

HRA and transparency

- Active commitment to promote transparency in research
  - For the HRA
  - HRA expectations
  - HRA requirements
- Recognise the different issues:
  - Registration
  - Results – findings (and different audiences)
  - Evidence and compliance and public confidence
  - Trial data
  - Tissue

Transparency – trial registration

- Clinical trial registration a condition of the REC approval from end September 2013
- Policy means for first 4 categories in IRAS Q2 it is a mandated condition
- Consideration remains for other study categories
- Expect registration by start of recruitment, a breach if not registered from 6 weeks of first recruitment in the UK
- Separate process to ask to defer (which will be recorded)

Transparency – next steps

- Develop simple mechanisms to monitor compliance – and build confidence in good conduct in the UK
- Seek views on proposals to update sponsor declarations (for new studies) to declare that previous studies have been registered
- Determine what we mean by publication, set standards by study type and audience – using focus on making research findings available
- Later, seek views on further use of REC declaration

Developing principles for good research - general

- UK wide steering group with ambition to issue a UK wide policy framework (which would enable the current frameworks to be withdrawn)
- Projects issued for comment to inform policy
- Policy issued for consultation as we become a NDPB
- RGF withdrawn when HRA policy adopted

Developing principles for good research – Informed Consent by simplified means; cluster and pragmatic trials

- Methodological Workshop December 2013
- NREAP discussions April 2014
- Pre-Consultation explorations June 2014
- *Consultation*
- *Policy - October 2014?*

Thanks for listening