



Health Research Authority Update

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To cover today...

- HRA Approval's current performance
- Changes and updates
- Top tips for a smooth assessment
- Other HRA news and updates





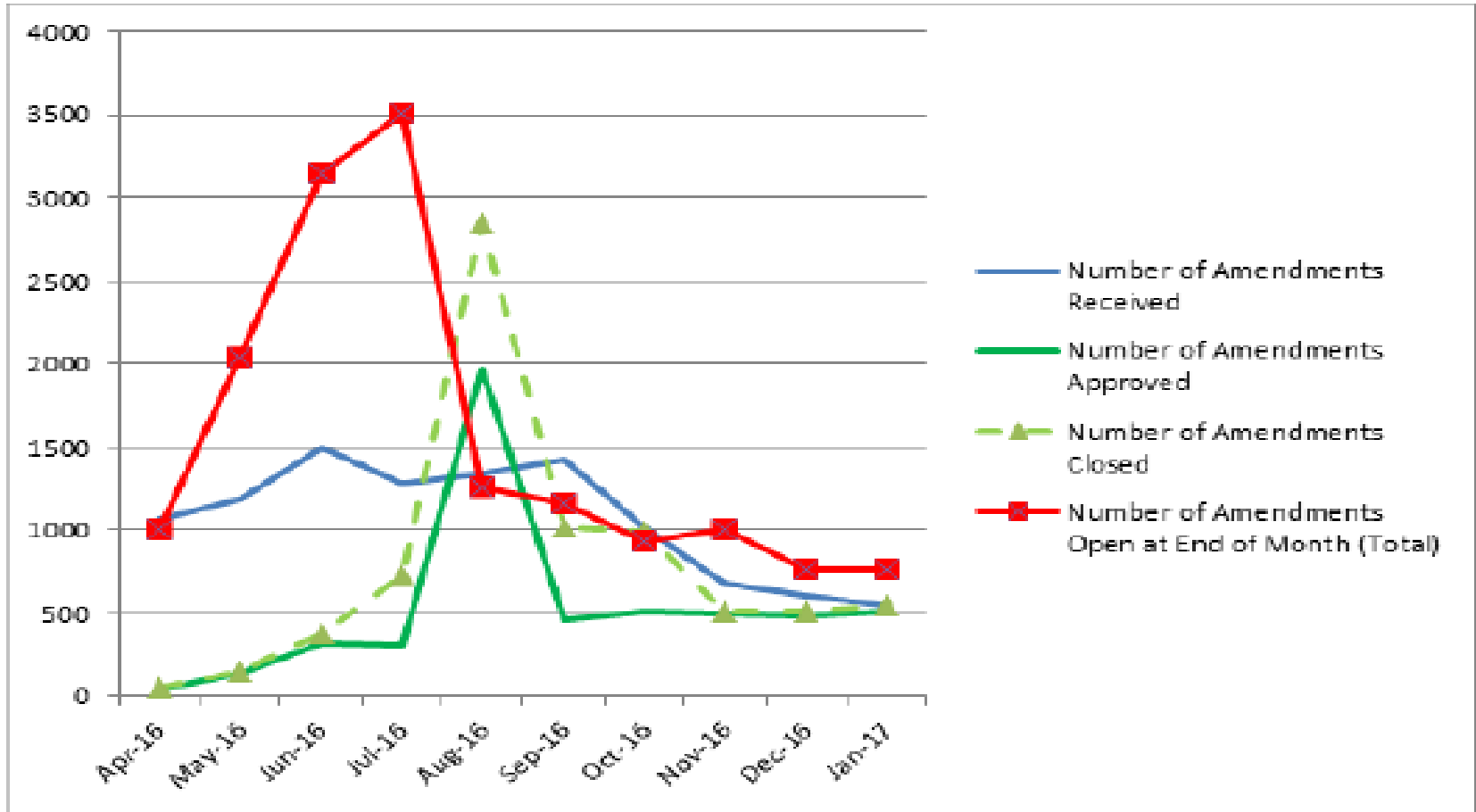
Current performance

Experience so far

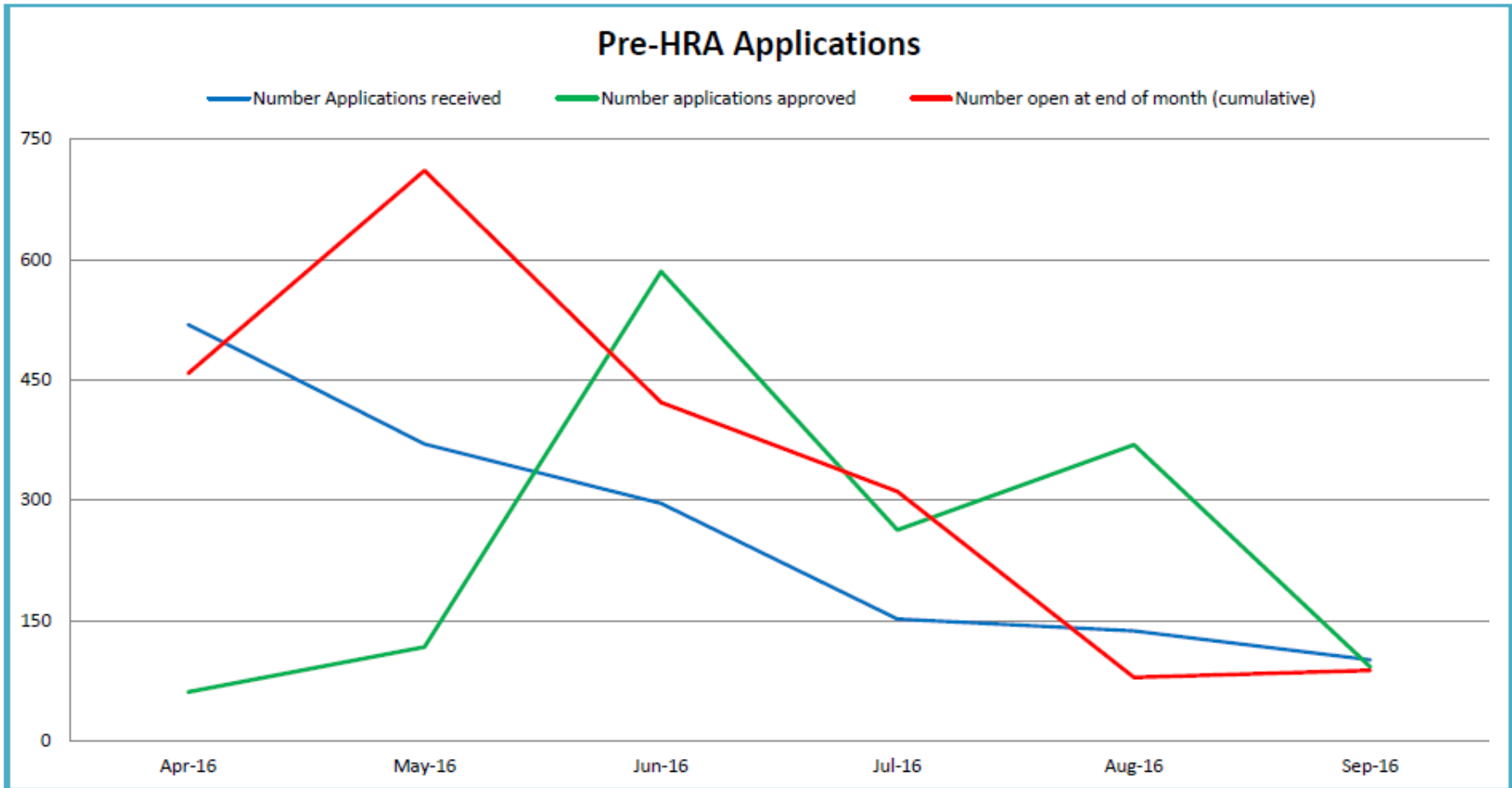
- Amendments
- Pre-HRA Studies
- New submissions



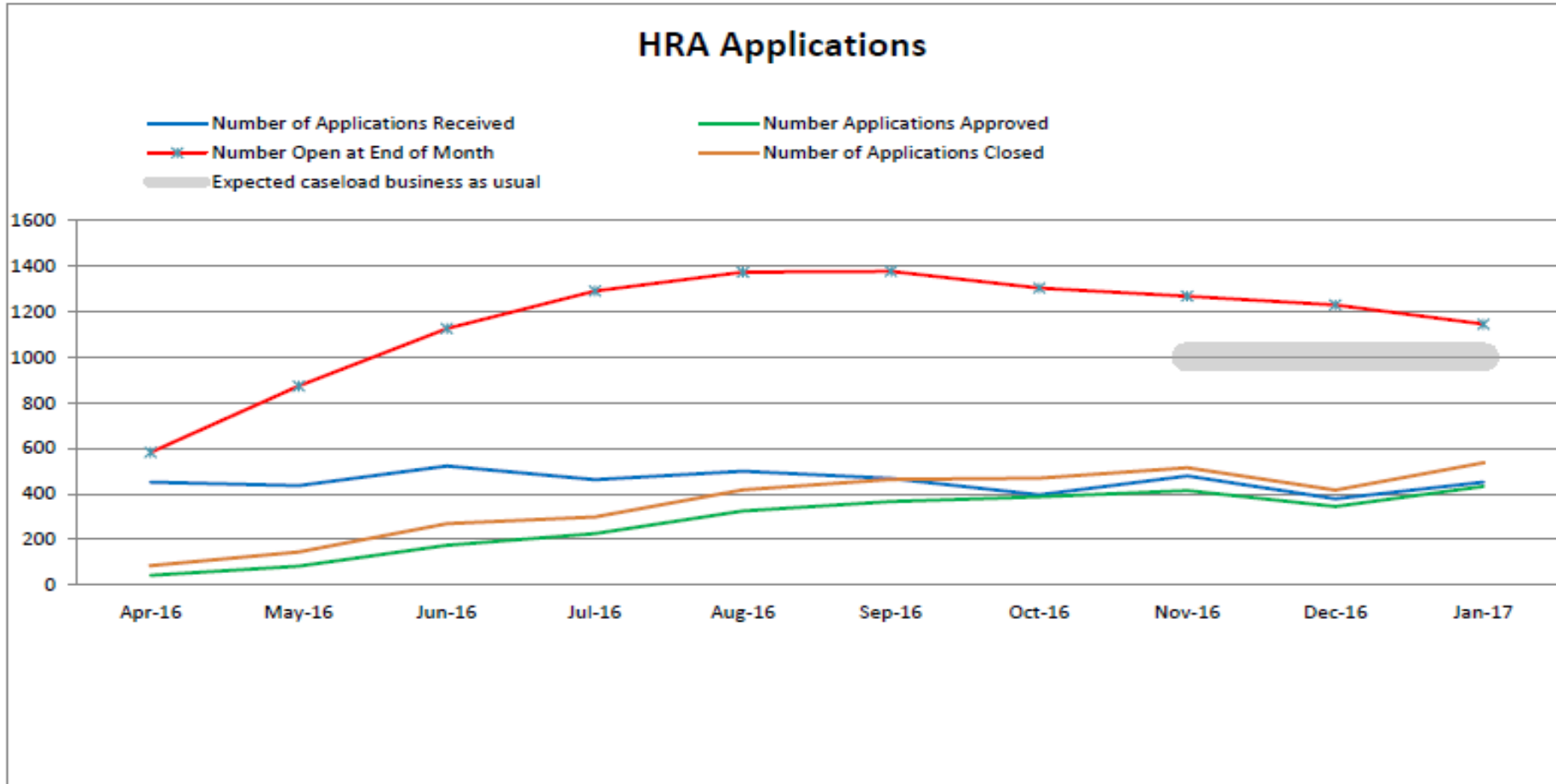
Amendment submissions and assessments



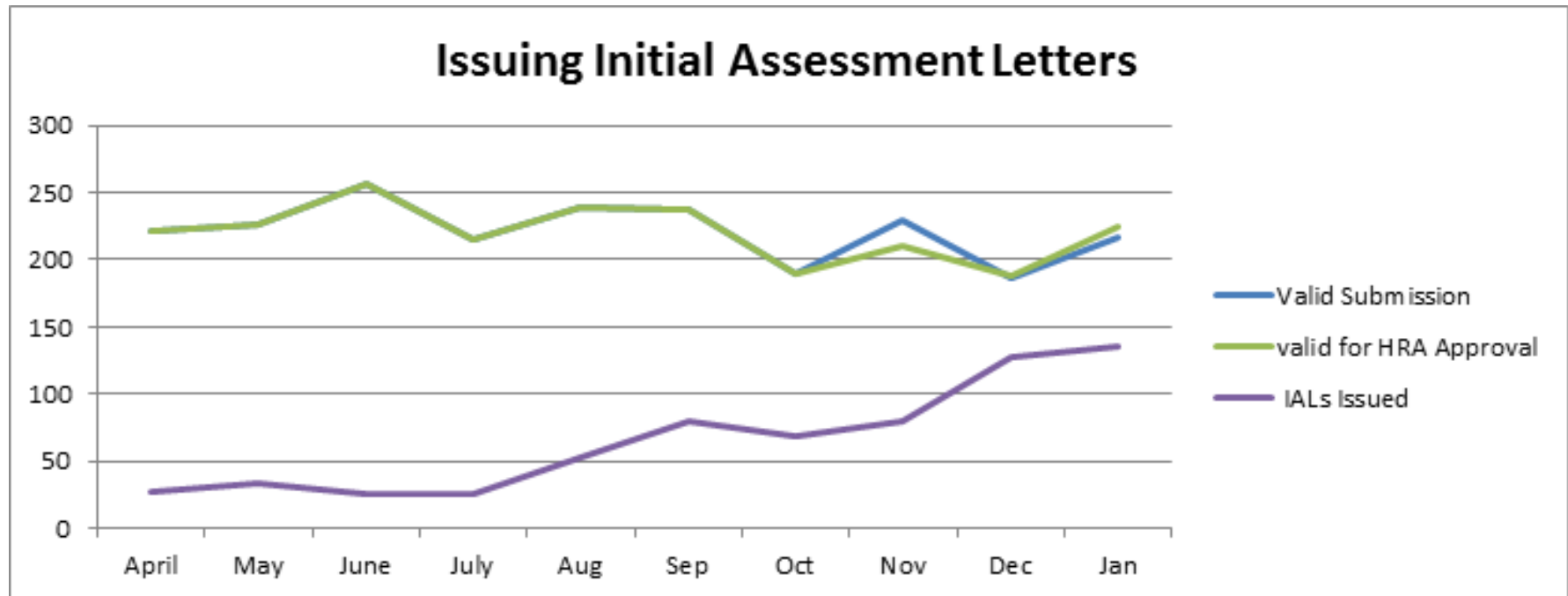
Pre-HRA Applications



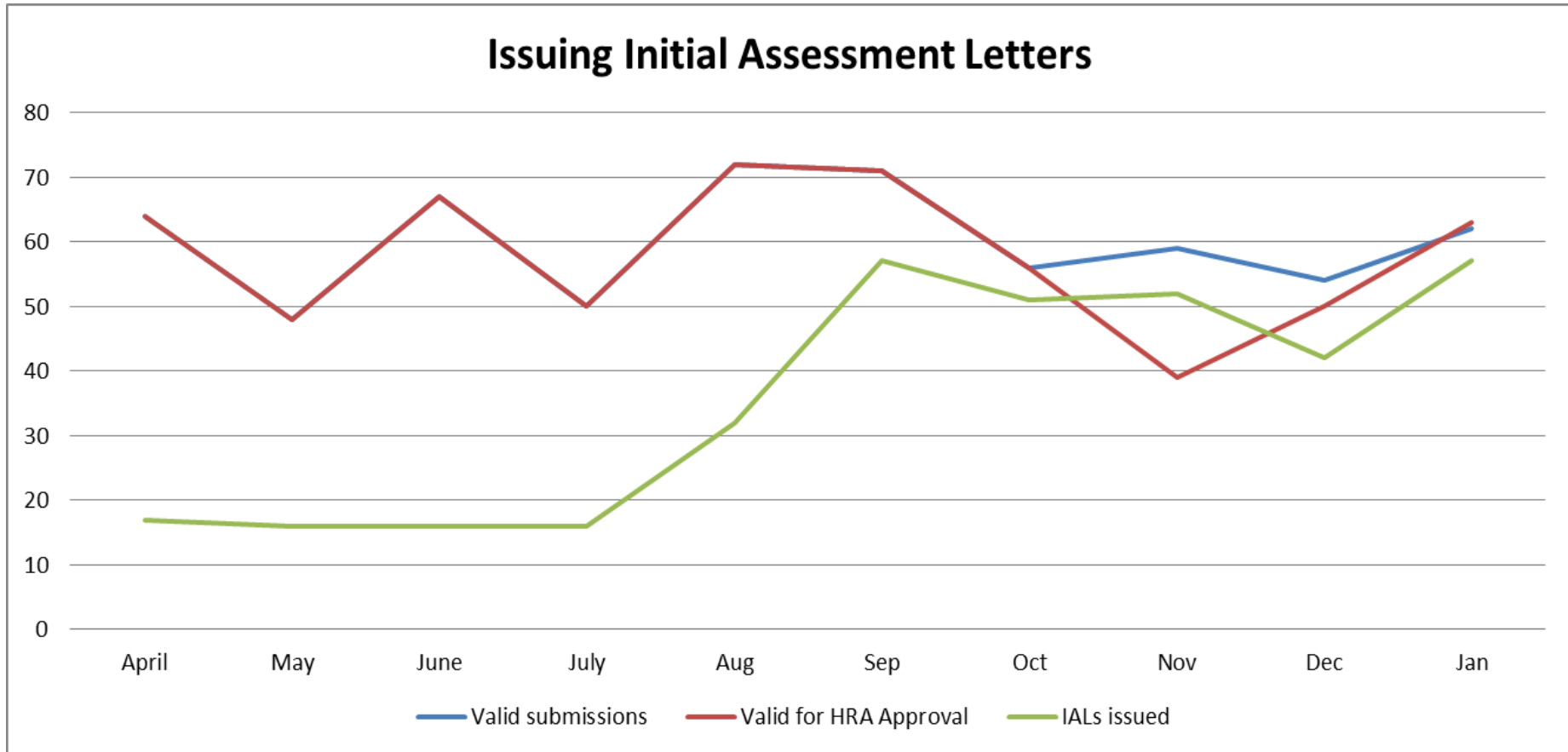
New study submissions



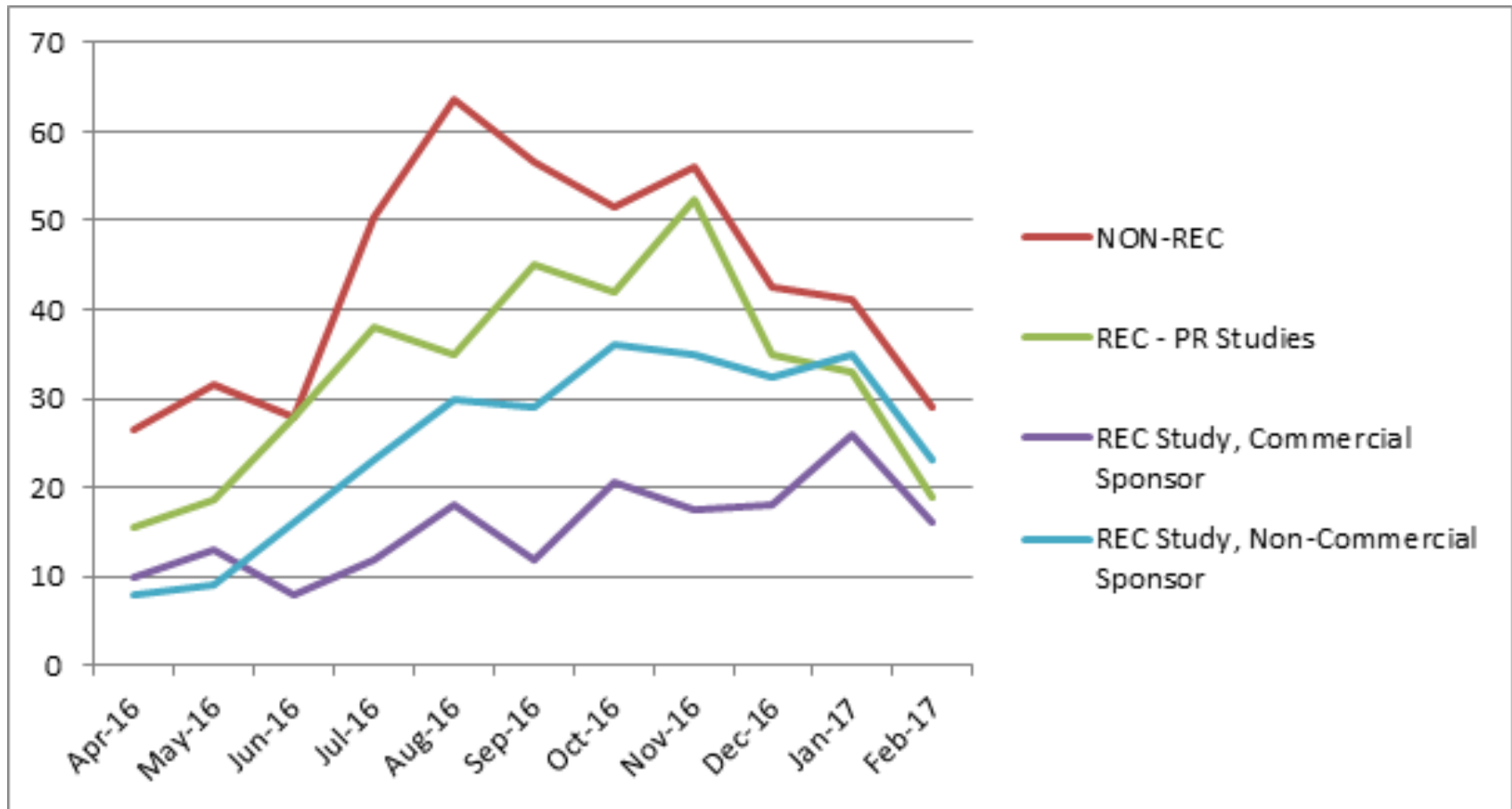
Initial assessments



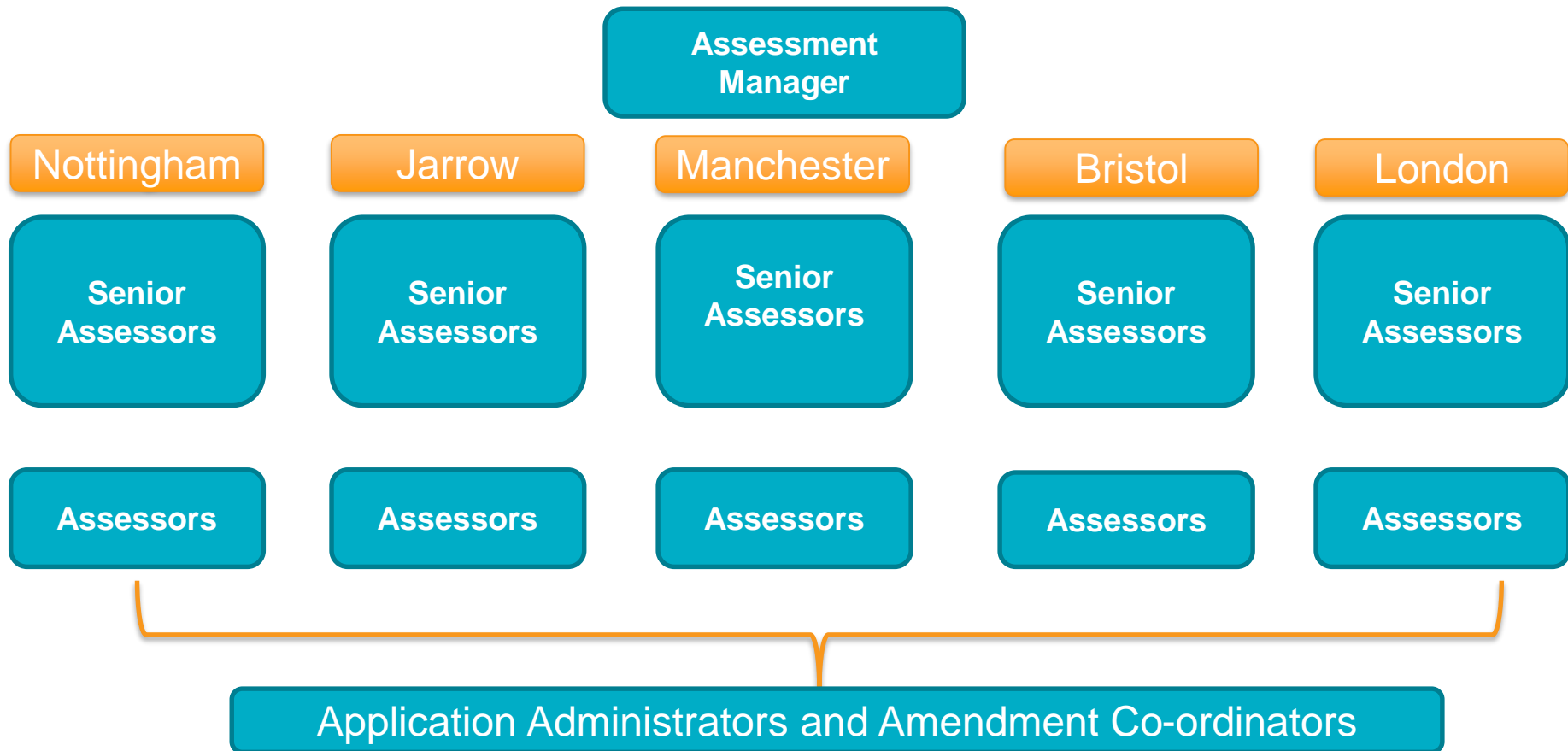
Initial assessments: commercial studies



Timelines for study assessments

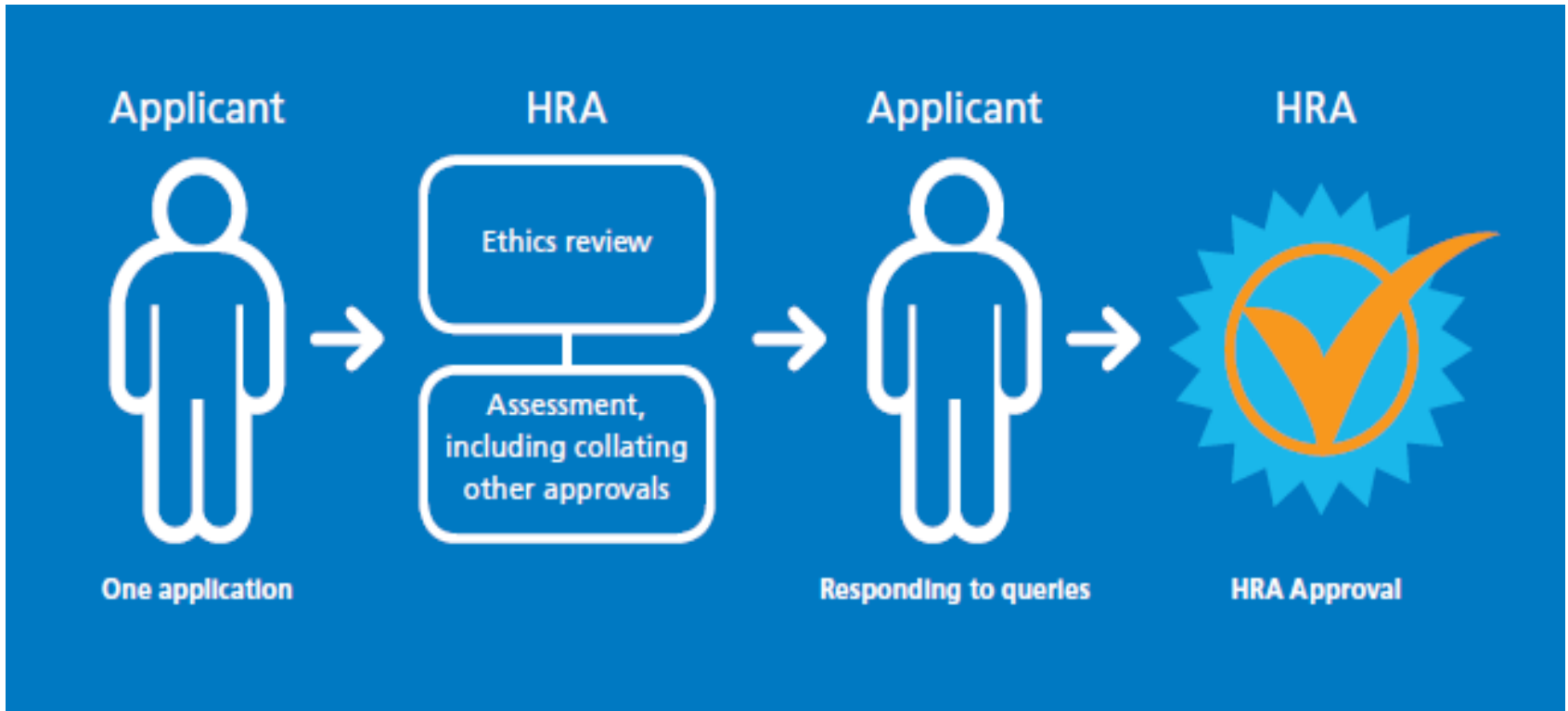


HRA Assessment Team





Updates



HRA Approval Process updates

- Amendment pilot on categorisation complete + triage introduction and development
- Further integration with REC and Approval teams
- SIP moving forward - focus on guidance, proportionality, amendments and process
- Contract clarifications on way
- Team training plan in place





Top tips for a smooth assessment...

To make your lives easier...

- Use the network support
- Look at the standards online before submitting
- Speak to us
- Review documents for consistency



What are we seeing?

- > 40% of applications are incomplete
- ~30% of applications for portfolio studies are submitted with costing template not yet validated by the Lead CRN
- Use of model agreements (for all UK nations) – with clarity on any modifications
- Any other agreements (e.g. CDA, MTA, etc.)?
- Copy/paste answers in IRAS not reflecting the study
- Information governance inconsistencies – protocol, ICF/PIS, IRAS, Lab manual, GP letter, etc.
- IRAS numbers missing on PIS/ ICF



Devolved administration consistency

- New role has been established to support cross working
- Setting out priorities to make submissions easier for applicants



England-led with cross border sites

Apply to HRA

HRA shares study-wide review with DA

DA does nation-specific checks

Apply with SSI for DA sites



Devolved Administration - led with English sites

Apply to DA and REC

DA shares study-wide review with England

HRA does nation-specific assessment and issues HRA Approval

Work with English NHS sites





Questions & queries



HRA Activity

Will Bowen– Collaboration & Development
Manager



Protocol Development tools

- Clearly defines the expected components of a protocol required by:
- Sponsors;
- Research Ethics Committees;
- Medicines Healthcare Regulatory Authority (MHRA);
- HRA Approval (England);
- NHS Sites



In line with:

- EU Regulation
- ICH GCP
- SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist



Protocols which have regard for the tool are less likely to raise queries that can cause delays.



The screenshot shows a web browser window displaying the HRA Training Tools page. The browser address bar shows the URL www.hra.nhs.uk/training/tools/. The page has a dark blue header with navigation links: HRA Training, Glossary, Vacancies, and Contact Us. A search bar is located on the right side of the header. Below the header, there is a main navigation menu with links for Home, Patients and the public, Research Community, REC and REC community, About us, and Resources. The current page is identified as HRA Training > Tools. On the left side, there is a sidebar menu with options for HRA Training, Training days, Tools (which is highlighted), and eLearning. The main content area is titled 'Tools' and contains the following text: 'The HRA, in collaboration with others, have developed a number of tools to assist researchers and sponsors in making high quality applications and to navigate the regulatory landscape:'. Below this text, there are four links: 'CTIMP Protocol development tool [Word doc]', 'Qualitative Protocol development tool [Word doc]', 'HRA/MRC Consent and PIS and preparation guidance [external link]', and 'HRA Approval Training Resources [internal link]'. At the bottom of the page, there is a footer with links for Accessibility, Site map, Cookie policy, Terms & conditions, and Feedback & concerns. Social media icons for Twitter, RSS, and IRAS are also present in the footer.



Other Activity



- Proportionate Consent
- Biobanking- UKCRC/HRA
- Social Care
 - AFRE Framework
 - OU online survey
 - Horizon Scanning for LA research leads
- Non-Commercial Sponsors workshop/MRC, R&D Forum/HRA



- BREXIT





Questions & queries
