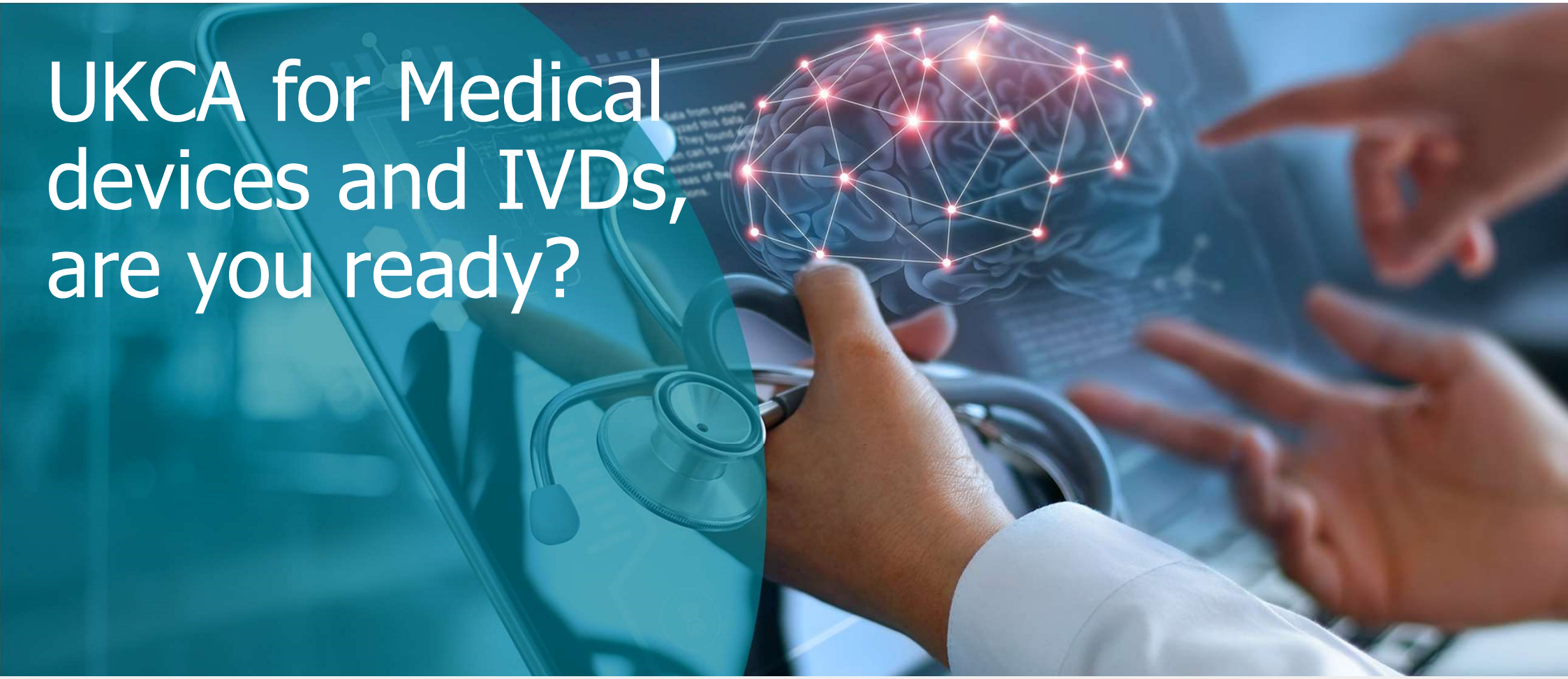
UKCA for Medical devices and IVDs, are you ready?



Jayanth Katta
Senior Regulatory Lead & Head of UK Approved Body

12 January 2021

By Royal Charter

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Dr Jayanth Katta, Senior Regulatory Lead & Head of UK Approved Body

Agenda

- Re-cap on future UK legislation of Medical Devices
- BSI UK as a UKAB
- BSI UKCA Conformity Assessment Model
- Next Steps

- Information presented within this webinar is based on our current understanding of the UK MDR 2002 and various guidance documents published by the UK Government

Re-cap – Key points of the amended UK MDR 2002

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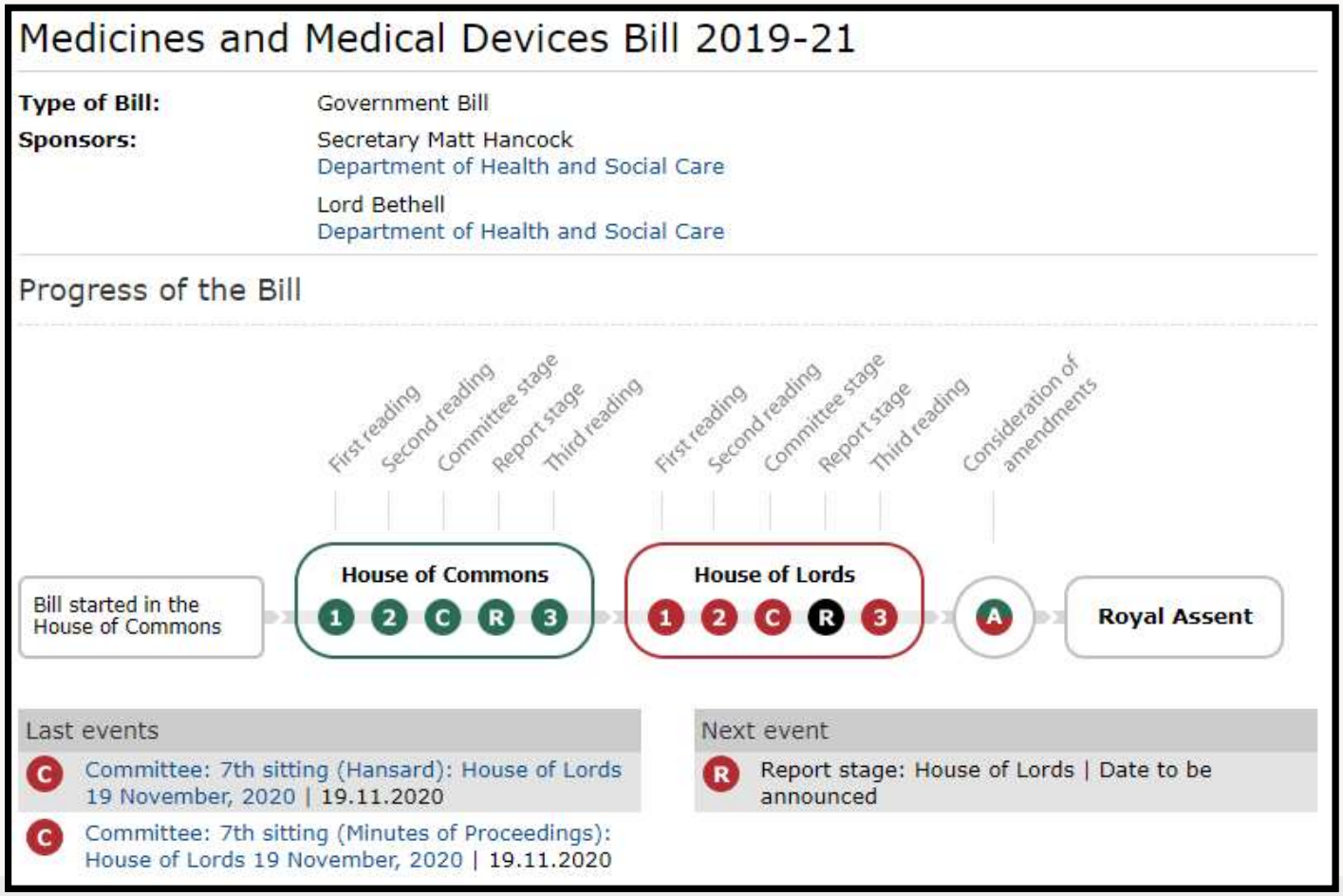
UK MDR 2002 (as amended) – Key Points

- GB Legislation based on Directives (as retained EU law) with some modifications; MDR, IVDR will not apply
- NI will operate under EU principles; MDR, IVDR apply
- UKCA product marking introduced in GB for medical devices
- UK Responsible Person (UKRP) required for manufacturers based outside UK
  - Only one UKRP allowed per legal manufacturer
  - UKRP needs to be appointed by 01 Jan 2021
- Device registration requirements introduced
  - All devices to be registered prior to placing them on the UK market
  - Grace periods available for initial registration based on classifications of devices
- UK based EU NBs became UK Approved Bodies (UKABs) from 01 Jan 2021 – Designations rolled-over
- UK will recognise EU CE marking until June 2023 to ensure supply of devices in UK; UKCA marking mandatory after that date
- Secondary legislation to be introduced via the UK MMD Bill (currently progressing through parliament)

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk
https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021#how-to-use-the-ukca-marking
https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices-from-1-january-2021

Progress on secondary legislation – UK MMD Bill



https://services.parliament.uk/bills/2019-21/medicinesandmedicaldevices.html

What product marking will get you where?

CE

GB	NI	EU
✓ Until 30 Jun 2023; NI trader exemption	✓	✓

UKCA

GB	NI	EU
✓ Can be used from 01 Jan 2021, but mandatory from 01 July 2023	✗	✗

UKCA + CE

GB	NI	EU
✓	✓	✓

UKCA + CE + UK(NI)

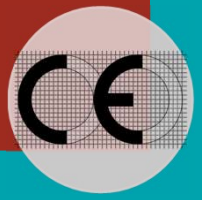
GB	NI	EU
✓	✓	✗

CE+UK(NI) is to be applied when a UK based CAB conducts conformity assessment against EU requirements. Devices bearing the UK(NI) mark cannot be further circulated into Europe after being placed in the NI market

General Labelling Principles

- No additional UKCA mark to be applied to labels
- Manufacturers outside UK must appoint UKRP, but not mandatory to identify UKRP on labelling

Devices placed on GB market based on CE certification / CE marking



- Labelling must use the UKCA mark as appropriate
- Manufacturers outside UK must appoint UKRP, and identify UKRP on either labels or IFU

Devices placed on GB market based on UKCA certification / UKCA mark

BSI UK 0086 as a UK Approved Body

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Published 3 December 2020
From: Department for Business, Energy & Industrial Strategy

Body number: **0086**
Last updated: **31 October 2019**
Body type: **Approved body, Notified body (NI)**
Registered office location: **United Kingdom**
Testing locations: **United Kingdom**
Website: **www.bsigroup.com**
Email: **Medical devices: MedicalDevices@bsigroup.com / Other areas: regulatory.enquiries@bsigroup.com**
Phone: **+44 (0)845 080 9000**
Legislative area: **Construction products, Gas appliances and related, Lifts, Marine equipment, Measuring instruments, Medical devices, Personal protective equipment, Pressure equipment, Transportable pressure equipment**

https://www.gov.uk/uk-market-conformity-assessment-bodies/bsi-assurance-ltd

BSI Assurance UK Ltd Medical Devices Scope

PDF, 146KB, 7 pages

This file may not be suitable for users of assistive technology.

▶ Request an accessible format.

BSI Assurance UK Ltd Active Implantable Medical Devices Scope

PDF, 94KB, 2 pages

This file may not be suitable for users of assistive technology.

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BSI Assurance UK Ltd In vitro Diagnostics Medical Devices Scope

PDF, 115KB, 4 pages

This file may not be suitable for users of assistive technology.

▶ Request an accessible format.

https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies

BSI UK (0086) – UKAB

2 EU NBs

(BSI 0086 & BSI 2797)

Until 31st Dec 2020

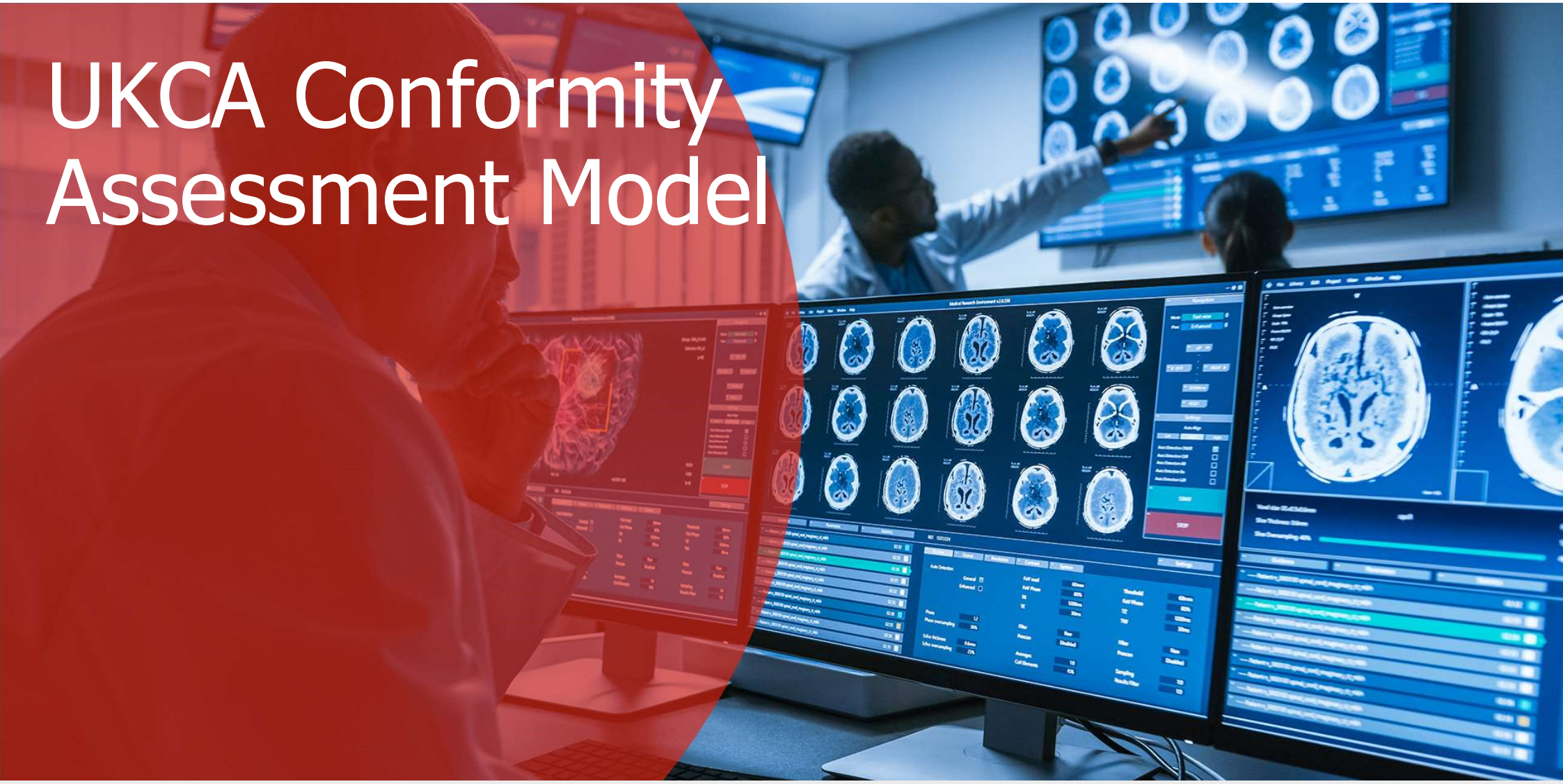
1 EU NB (BSI 2797)

&

1 UKAB (BSI 0086)

From 1st Jan 2021

UKCA Conformity Assessment Model



Scenario #1 – Manufacturer with initial applications for CE marking or CE certificates issued by BSI 0086 prior to 01 Jan 2021

- Any on-going initial applications will proceed as normal; instead of CE certificates, UKCA certificates will be issued at the end of the process

- CE certificates issued prior to 01 Jan 2021 will continue to be valid for GB after that date
  - At the first re-issue (change or renewal) or 30 June 2023 whichever is earlier, they will be converted to UKCA certificates

- All surveillance activities to continue as per existing arrangements, but UKCA requirements related to registrations, UKRP etc will be checked during future NB audits

Documents required to convert CE certificate to UKCA certificate:

Draft UKCA labelling
Draft Declaration of Conformity
Evidence of appointment of UKRP (if applicable)
Evidence of a labelling transition plan (if applicable; maximum transition period – 6 months)

Scenario #2 – New UKCA applications with no prior certification

Current Directive certification processes will apply in full

UK specific requirements related to UKCA marking, UKRP, and device registrations – covered during assessments

Device drug consultations – undertaken with MHRA

Devices with animal tissue derivatives with TSE risk – Technical review by MHRA to replace the European SER commenting process

Scenario #3 – UKCA Applications for manufacturers holding Directive/Regulation certificates issued by BSI NL NB 2797

- Abridged conformity assessment process where possible

- Gather and summarise evidence from prior assessments
- Current compliance status (any outstanding Major NCs?)
- Validity of any consultations previously conducted considering any changes to the devices (for device-drug combinations and devices utilising animal tissue derivatives with TSE risk) – Specialist Review
- Review of UK specific requirements - DoCs, UKCA labelling and UKRP information

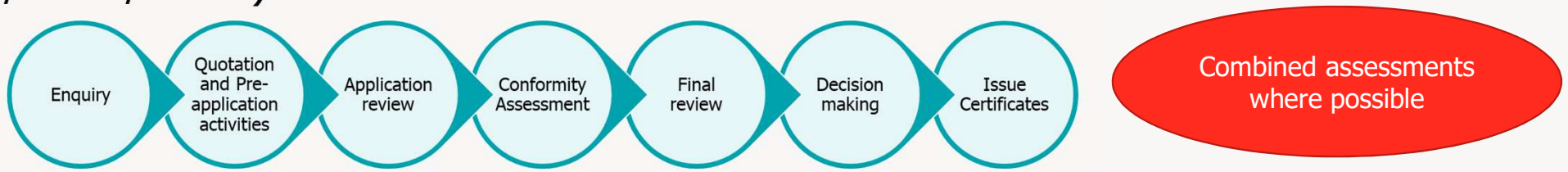
Additional assessments may be required in some cases

Scenario #4 - UKCA Applications for manufacturers holding MDR/IVDR/MDD/AIMDD/IVDD certificates issued by other non-BSI EU NBs

- Conformity assessment to follow principles of EC certificate transfer (although not a true transfer)

- Pre-Transfer Technical Documentation Review
- QMS Transfer audit – Typically 1 day
- Sampling of Technical Documentation for IIa/IIb/List B devices
- Transfer dossier reviews for each Class III/AIMD/List A devices
- Validity of any consultations previously conducted considering any changes to the devices (for device-drug combinations and devices utilising animal tissue derivatives with TSE risk) – Specialist Review
- Review of UK specific requirements – incorporated into the above assessments

Scenario #5 – Combined initial applications – UKCA + EU legislations (MDR/IVDR/IVDD)



Quality Management System Audits (including Microbiology audits if required)

- Combined QMS audits
- Combined Microbiology audits
- Extra time (~0.5 day) added to the normal Stage 2 and Recertification audits to cover two sets of legislative requirements

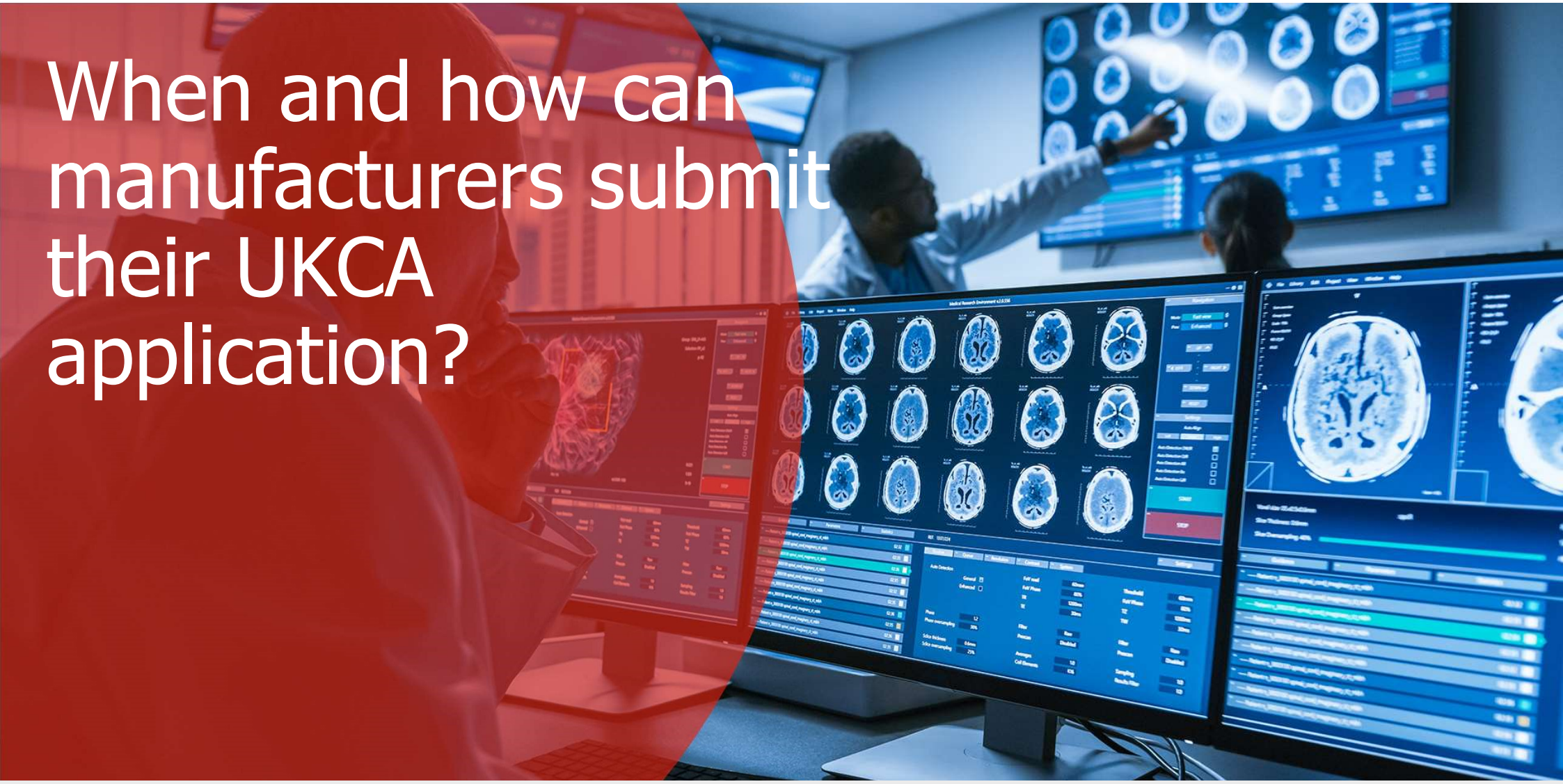
Technical Documentation Reviews (if required)

- Combined Technical Documentation Review process for MDR+UKCA and IVDD + UKCA
- Additional time added per device to cover two different legislations and reporting requirements (~ 0.5 day/per device selected for review)
- Separate reviews for IVDR and UKCA (IVDD) due to significant differences in the requirements between IVDD and IVDR

Other elements

- Combined unannounced audits where possible. Separate audits maybe needed based on the scope differences of UKCA and EU certifications
- Separate consultations may be (TBC) required for each legislation for device-drug combinations
- Separate processes may be (TBC) required for devices containing animal tissue derivatives with TSE risk
  - UK – Technical assessment by MHRA
  - EU – SER commenting process

When and how can manufacturers submit their UKCA application?



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UKCA Applications

Enquiries:
Your BSI Account Manager or
MedicalDevices@bsigroup.com
(new enquiries)

By Royal Charter

Useful Resources

https://www.bsigroup.com/en-GB/medical-devices/resources/

https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/