



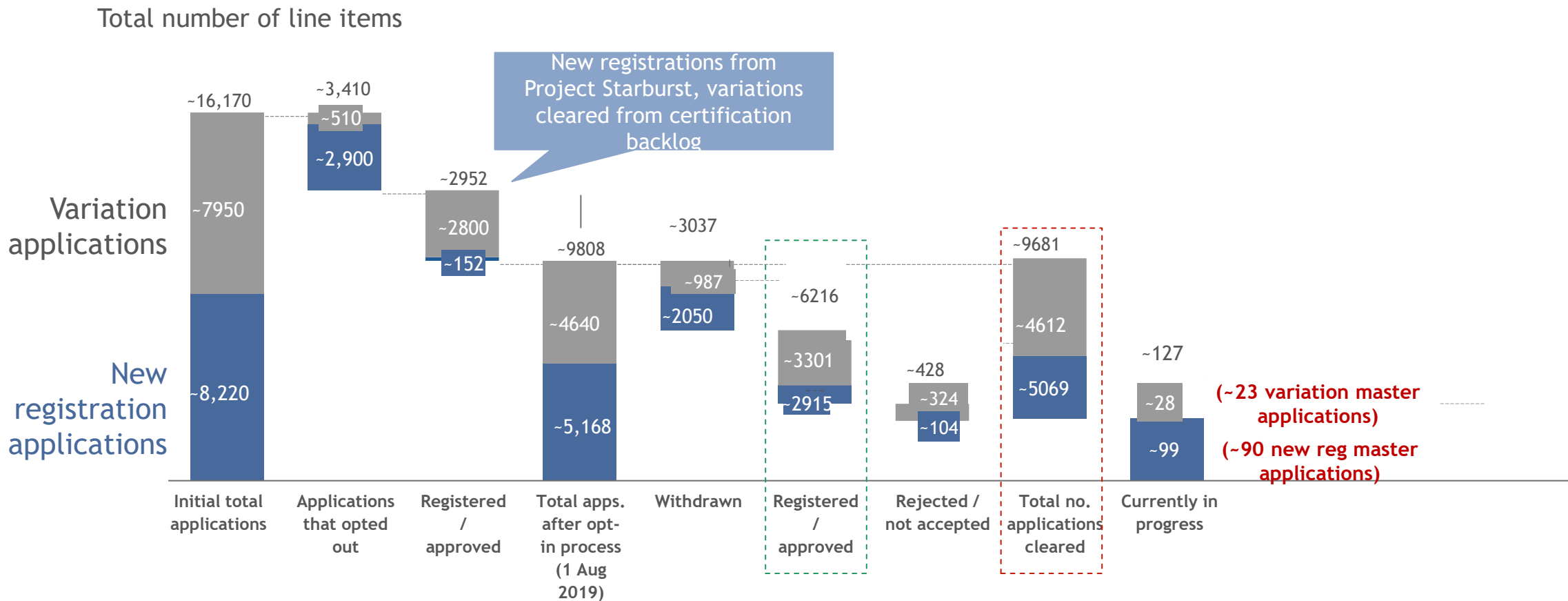
Backlog Clearance Project Performance Update

SAPRAA - 25 August 2022



Application backlog has been reduced by ~99,2% to date

Data as of 23 August 2022

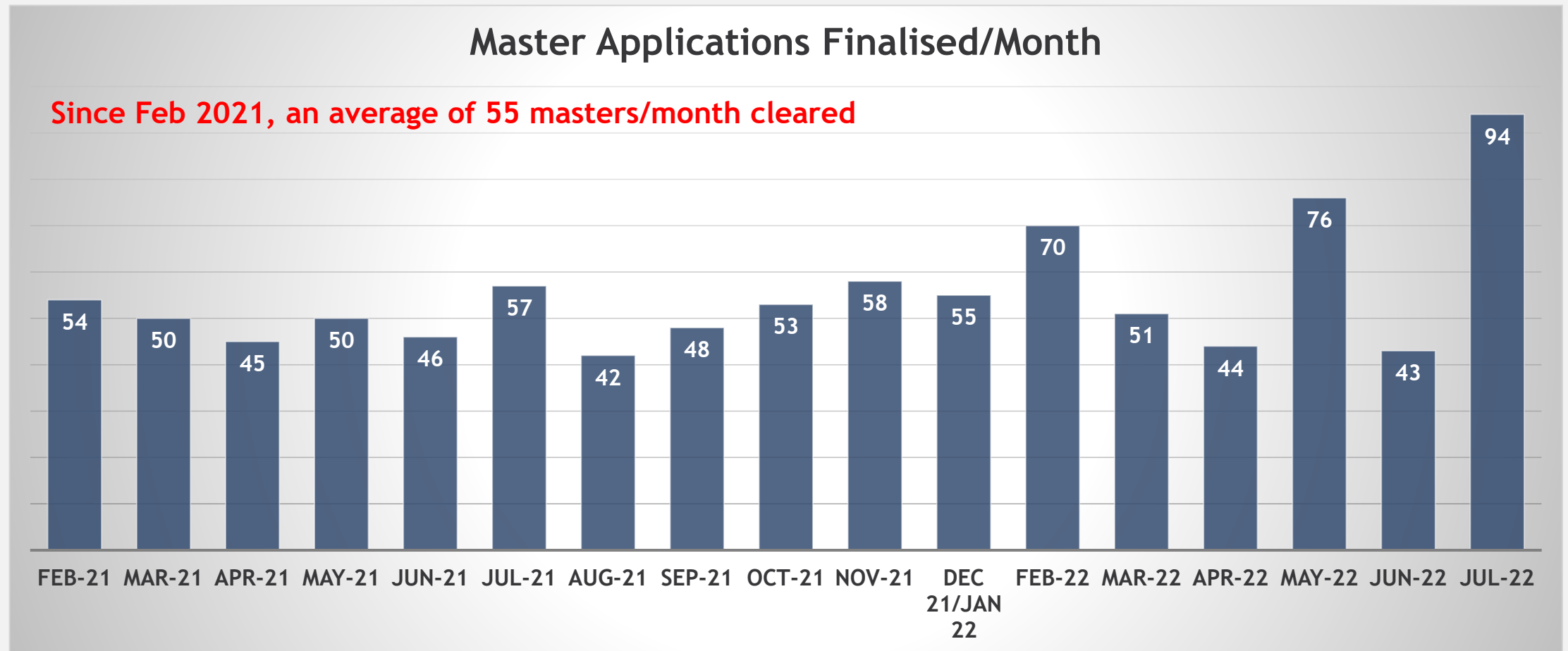


New Registration Applications



New registration applications cleared (masters) since February 2021

To date Aug 2022:
83 masters cleared



Includes all finalised applications, i.e. registrations, rejections & official withdrawals

Overall Clearance of New Registration Applications

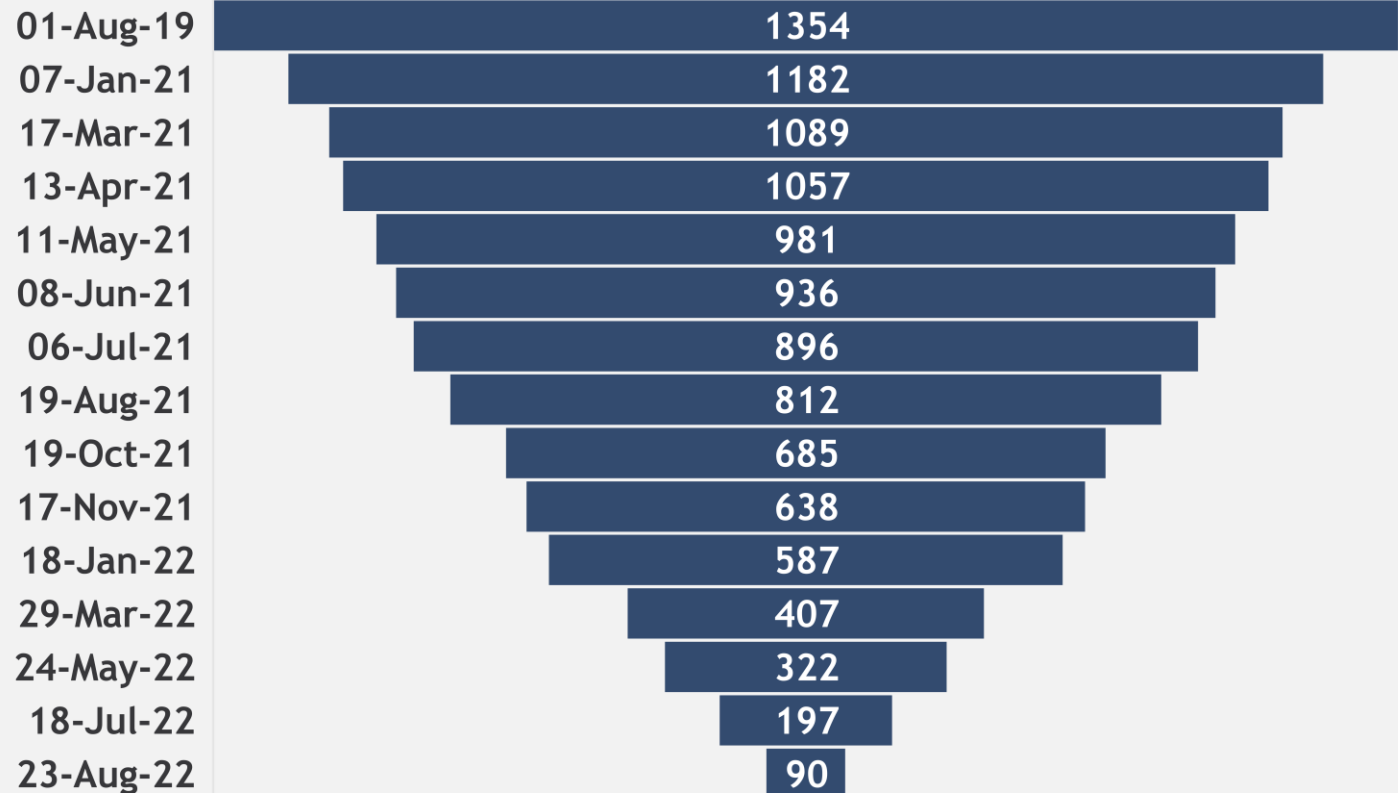
172 master applications cleared in 2020

583 master applications cleared in 2021

509 master applications cleared in 2022 to date

>1250 master applications finalised since Go-Live on 01 Aug 2019

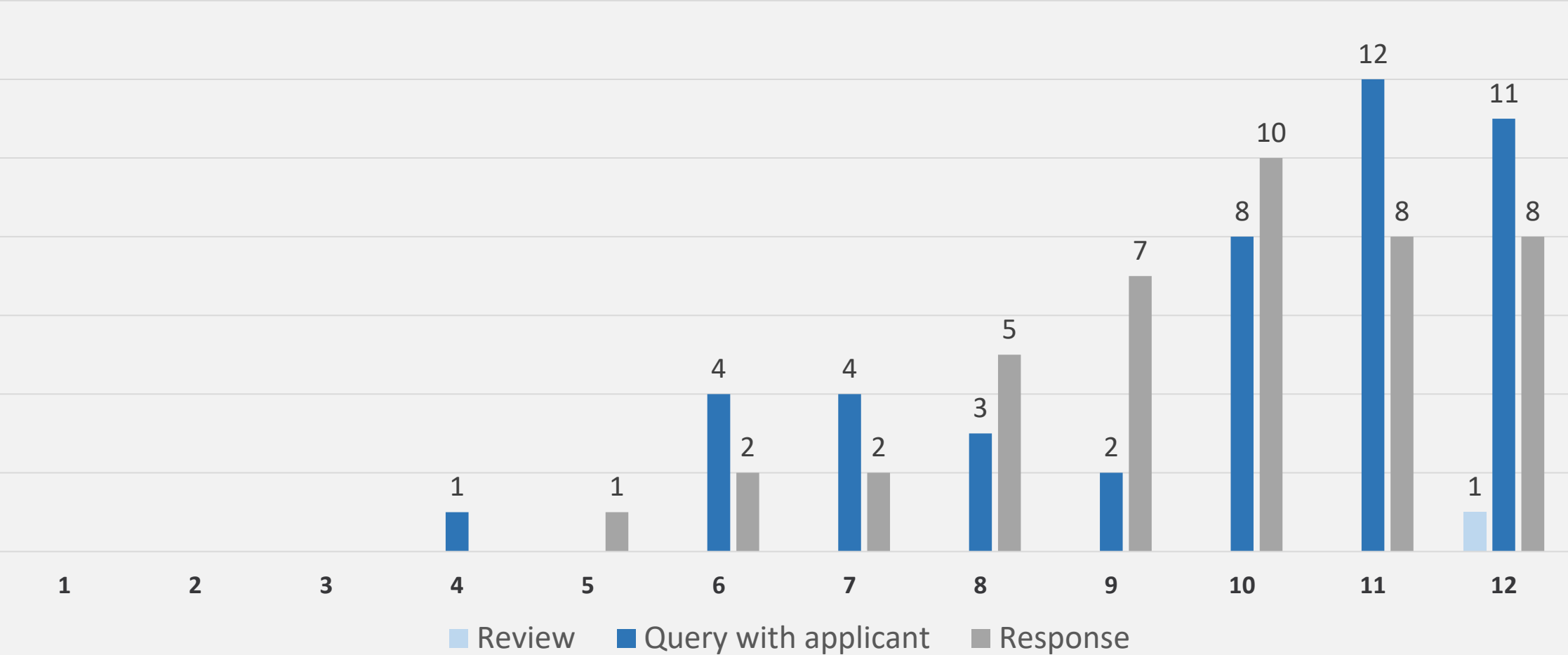
New Reg Master Applications awaiting Finalisation



Evaluation - In Progress

Data as of 19 August 2022

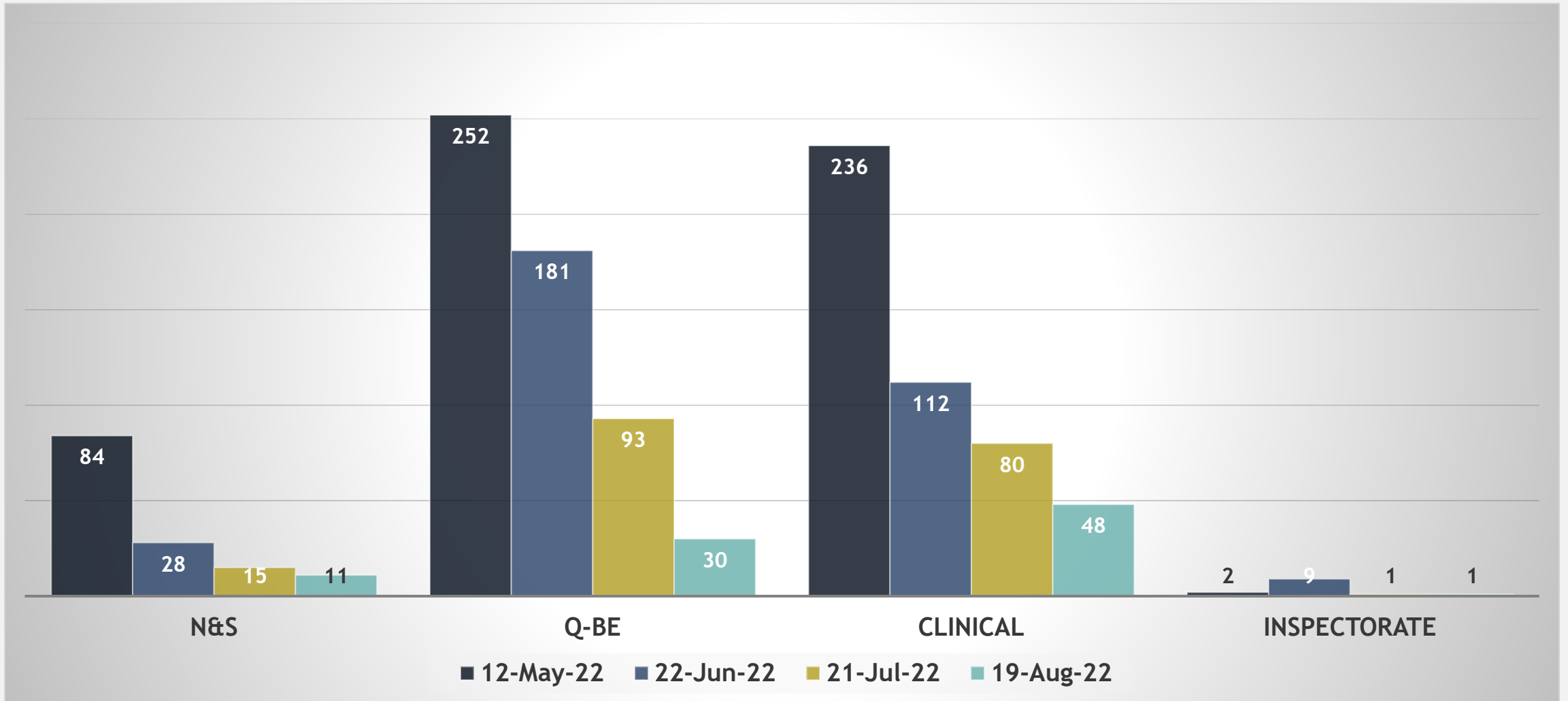
All applications in all units have been allocated.
Left with ~90 active master applications.
43% of applications query with applicant.





Data as of 19 Aug 2022

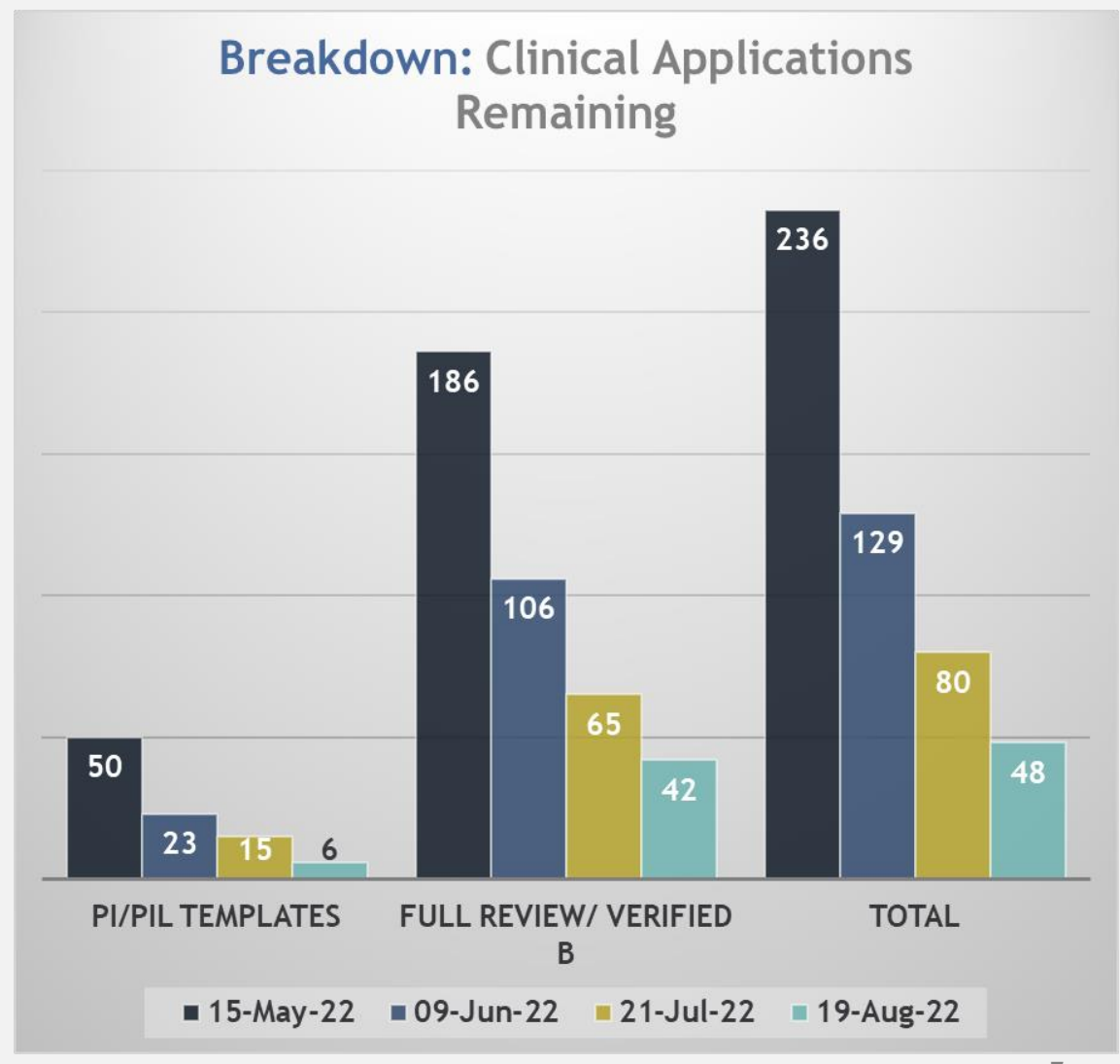
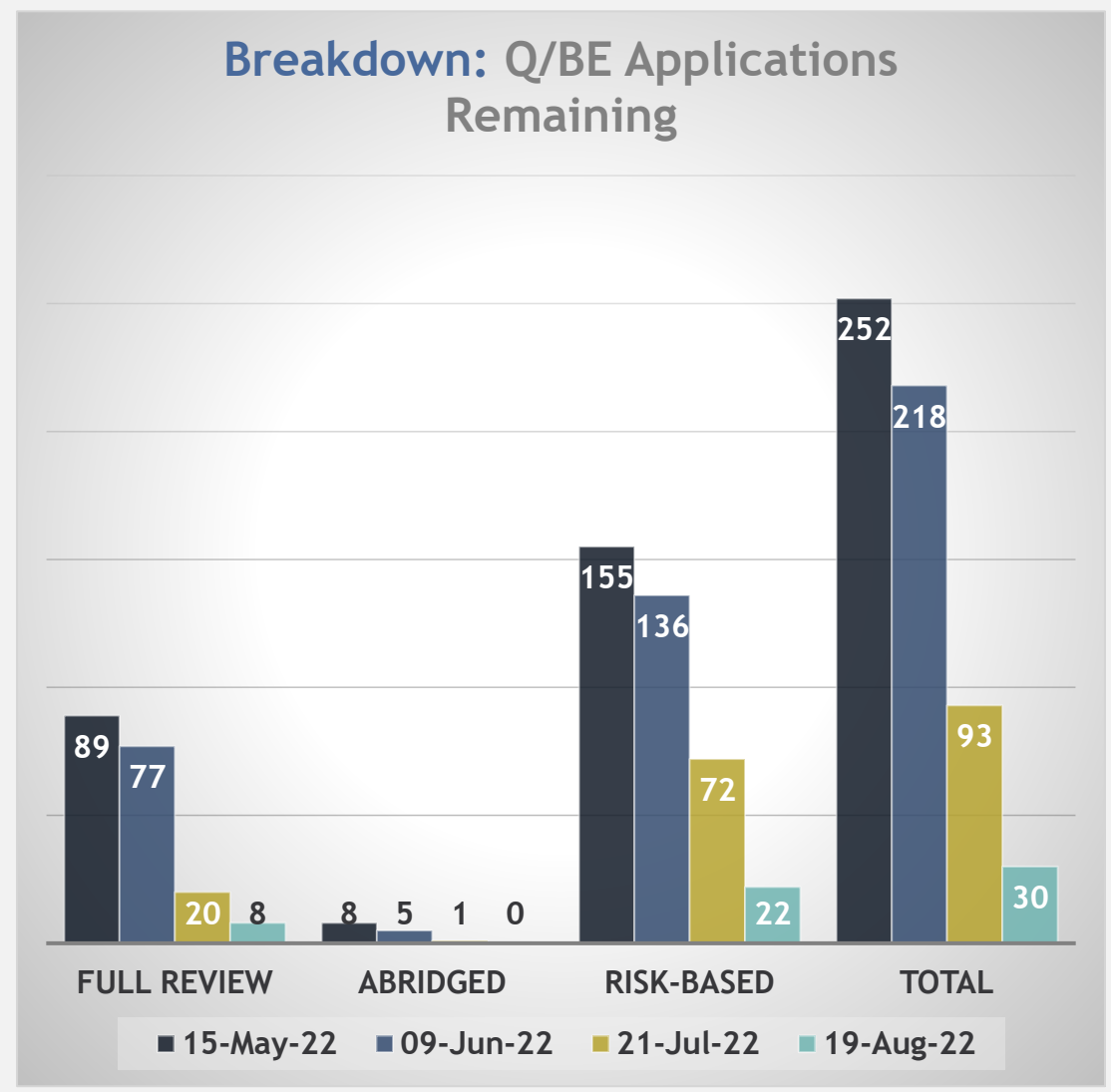
Applications per Unit Remaining





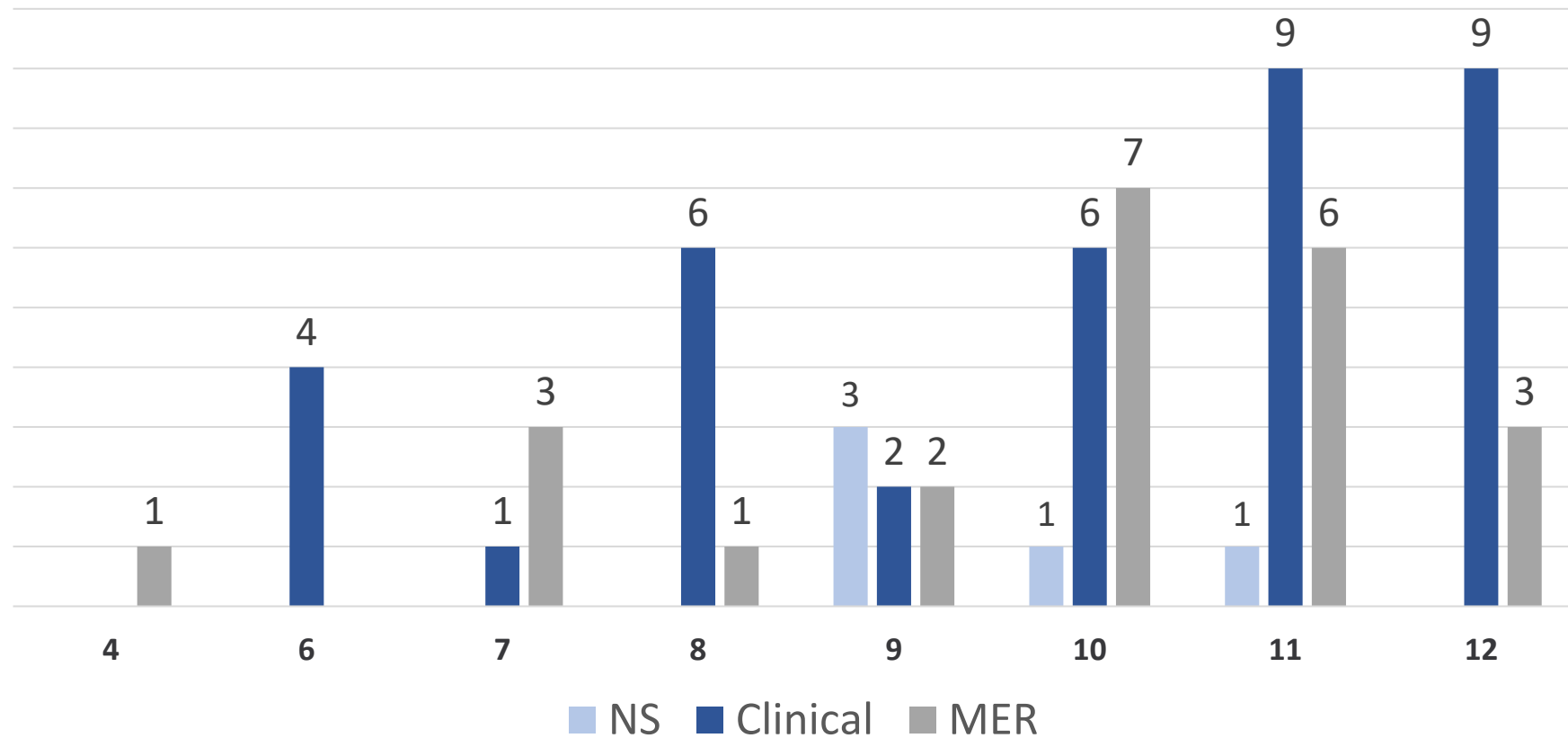
Data as of 19 Aug 2022

Applications per Unit Remaining



Applications with 3 Units Complete

Total Number = 65/90 = 72% of remaining applications only have one unit outstanding



Variation Applications

Distribution of variations across end-to-end process

Current status



Data as of 19 August 2022



Admin screening²



Technical screening



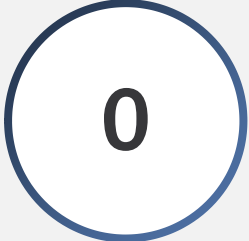
Evaluation



Approved or rejected³

Sum

Today



523

P&A
Clinical
Inspectorate
Multiple⁴

P&A	0
Clinical	0
Inspectorate	0
Multiple ⁴	0

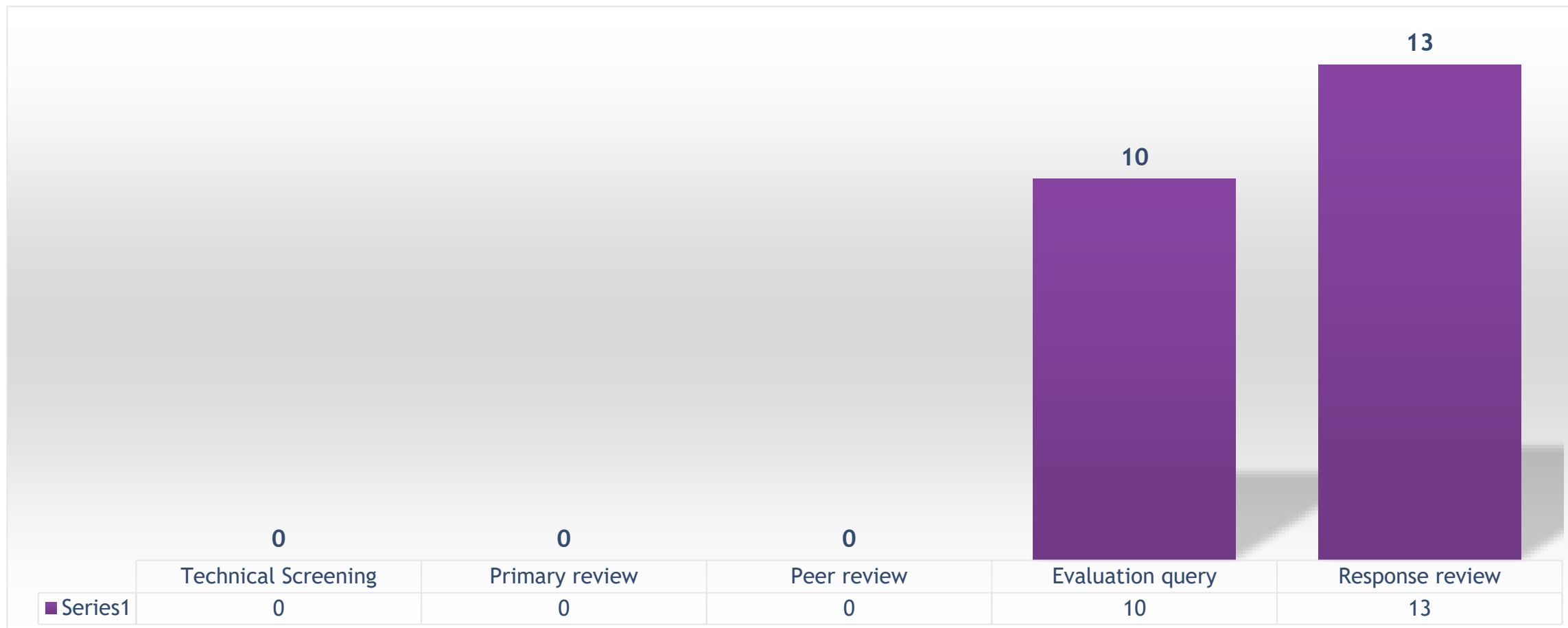
P&A	0
Clinical	0
Inspectorate	0
Multiple ⁴	0

P&A	0
Clinical	22
Inspectorate	0
Multiple ⁴	1

P&A	145
Clinical	234
Inspectorate	11
Multiple ⁴	35
Withdrawn/Rejection/BAU	75

Withdrawn/Rejection/BAU

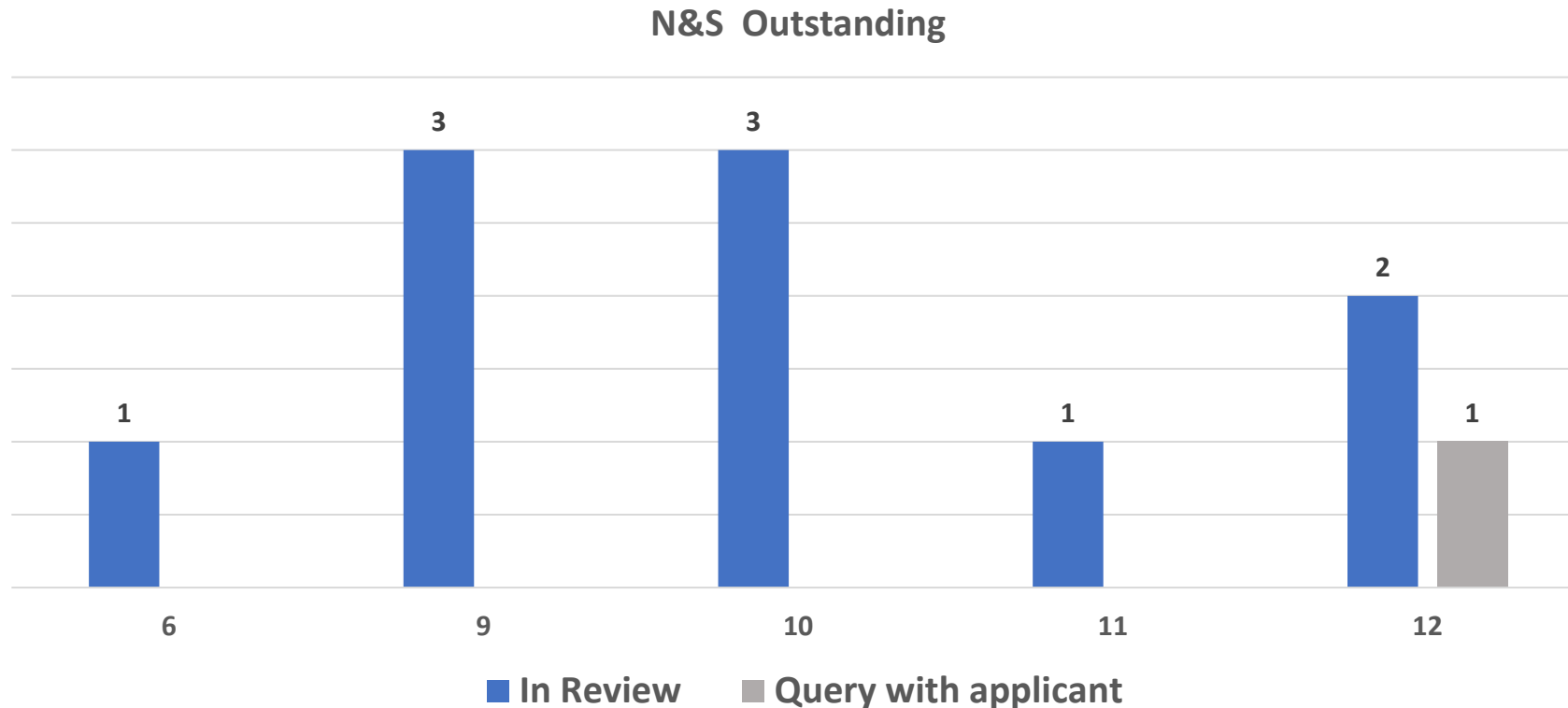
Deep Dive (Clinical) - Applications in Process



Inspectorate and N&S

Inspectorate and N & S Outstanding

- 1 Conditional approval left for Inspectorate. One FPRC still in inspection review.
- Total master applications remaining N & S: 11
 - 10 responses in review;
 - 1 application query with applicant.



Interventions - Risk-Based Assessment

Q-BE Risk-Based Assessment Pilot Study - Phase 1

Outcome of PHASE 1:

- Commenced 20 Sept 2021 - March 2022
- Wide internal & external consultation on Phase 1
- 63 (RW8) new registration master applications included in Phase 1
- However, 7 applications subsequently withdrawn by applicants (n = 56)
- All 56 applications **primary & peer reviewed in approx. 2 months**
- Disregarding one month of summer holidays, when both Industry and SAHPRA ran on minimal staff, **97%** of applications' Q & BE aspects had been **evaluated & concluded in approx. 4 months**
- Substantially reduced review and response timelines for Q & BE full review applications

Q-BE Risk-Based Assessment Pilot Study - Phase 2

In-Process PHASE 2:

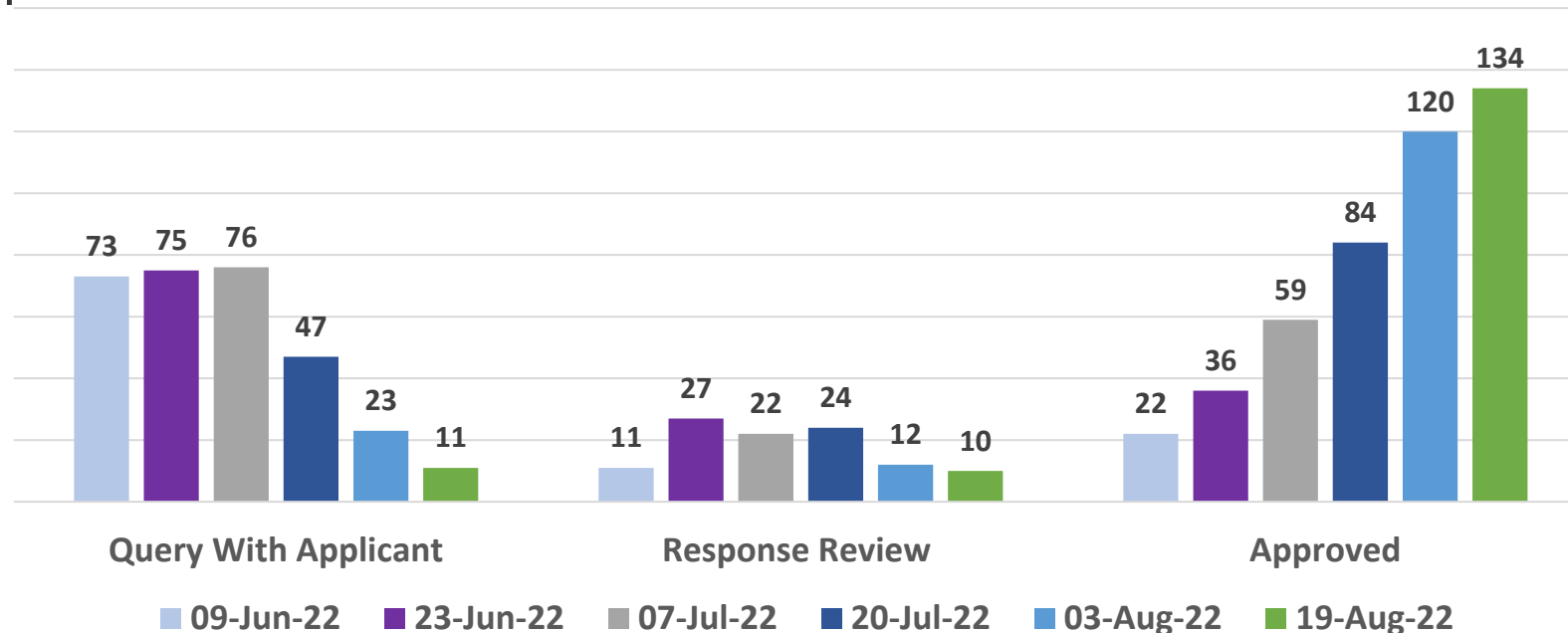
- Commenced in April 2022
- Remaining Q & BE full review applications in the Backlog Clearance Project (approx. 150-160 master applications) were included in Phase 2
- Larger cohort of evaluators (comprising of in-house, local & international); approx. 18 assessors utilised for Phase 2
- Again, peer review sessions convened; beneficial in reducing review time with added benefit of multiple experienced eyes looking at an application

Q&BE Risk-Based Assessment - Phase 2

Data as of 19 August 2022

STATUS UPDATE:

- Only 22 applications remaining in pilot study
- 21 applications remaining (primary and peer complete); one is being assessed by CAMS Committee
- 52% query with applicants of the 21 applications remaining
- 48% in response review of the 21 applications remaining
- And 86% approved of total 156



Conclusion

Projected Time to Clear Backlog

Data as of 23 Aug 2022

No. of applications still be in processed within Backlog Clearance Programme:

- ❖ ~90 New Registration Master Applications
- ❖ 23 Variation Applications

Projected Timeline for New Reg Applications:

	Clearing ~90 New Reg Applications (Masters)	Clearance Date
Best Case	60 finalized masters per month = ~1,5 months (projection based on planned interventions, e.g. risk-based assessment)	Mid Oct 2022
Average Case	50 finalized masters per month = ~2 months (projection based on 2021 throughput)	End Oct 2022
Worse Case	40 finalized masters per month = ~2,5 months	Mid Nov 2022

Backlog Team Transition

- Commencement with restreaming the Portfolio Coordinators (PCs) to HPA. There will be a change in PCs per applicant over the last few months of the project.
- New Evaluators Coordinator (EC) roles created in HPA, mirroring Backlog structure. These roles to be filled with Backlog staff.
- Out of the original 33 Backlog team, all except 8, have been permanently placed in BAU.
- Transfer of skill and knowledge gained in the Backlog Clearance Project to BAU.

Q&A

