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# Backlog Clearance Programme Update

SAPRAA - 18 November 2020

# Agenda

Performance Overview

Variations Update

Recognition Update

Q&A



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Performance Overview

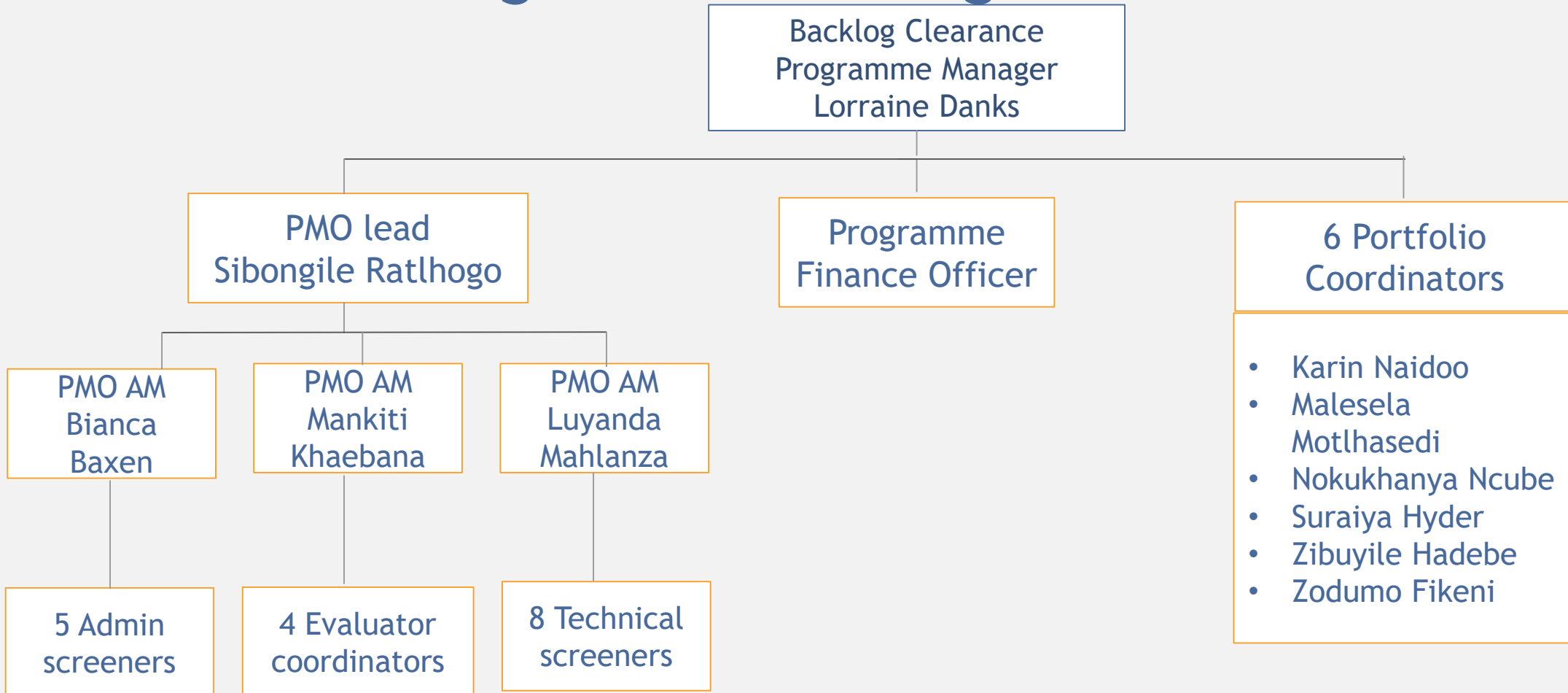
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# SAHPRA Backlog Clearance Programme Team

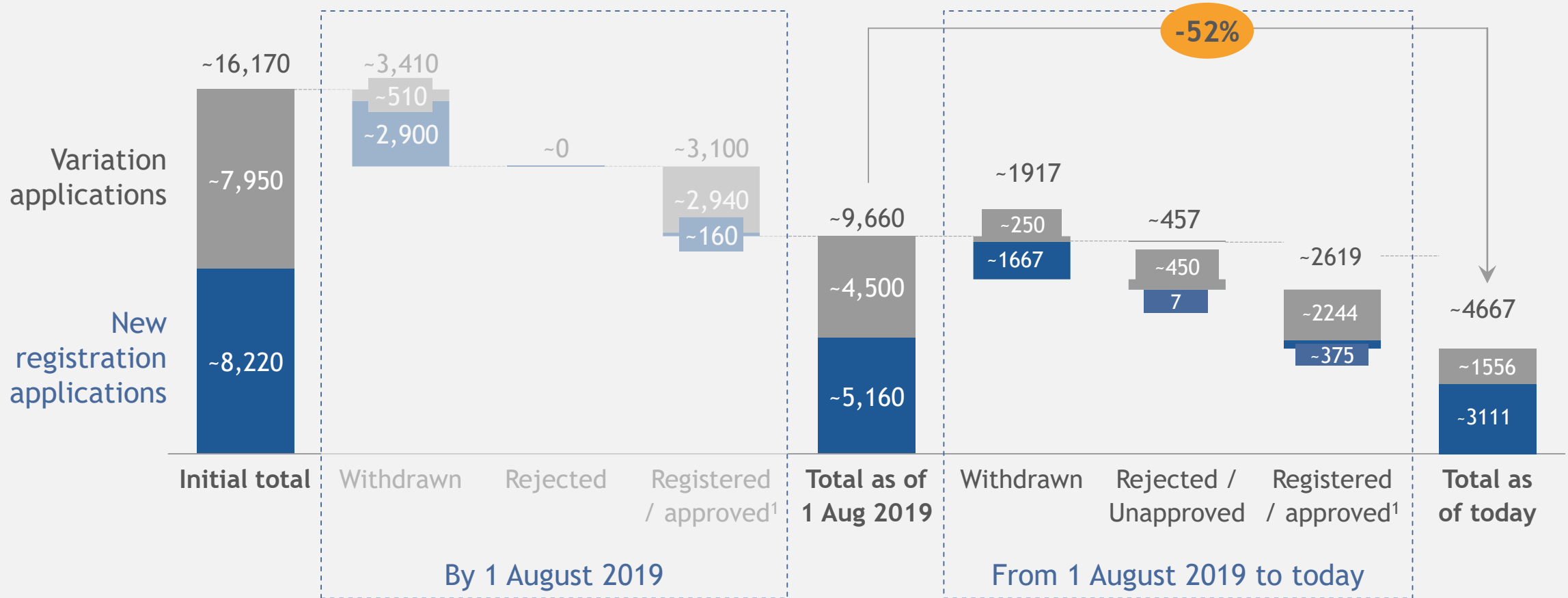




# Backlog Clearance Program update: Key messages

- A total of ~3,212 new registration applications have been resubmitted, ~65% of expected for RW1 to RW11 (Last window closes 30 Nov 2020)
- Majority of applications have progressed to technical screening and evaluation. However 28% of applications in technical screening and 55% of applications in evaluation have queries for applicants to address
- Due to Covid-19 pandemic, some applicants have not been able to respond to queries timeously and will resubmit in the special RW (Dec 2020):
  - 21(8) applications in technical screening
  - 102(43) application in evaluation
- Recognition Pilot underway-for RW 7 applications
  - 15 applicants expressed interest
  - 47 master applications currently underway
- Successful "soft-launch" of the Digital Variations Portal, with ~100 companies registering profiles and ~2204 Type I variations approved by Dec 2019  
366 Type II variation applications received and 162 are currently in evaluation

# The current backlog stands at ~4,667 applications, <30% of the original total of ~16,170 applications



1. Finalised, in the case of variation certificates; 2. Preliminary number based on high-level analysis of submissions through the Digital Variations Portal



# Clear targets have been set for progression and finalisation of backlog applications

## New registrations



### Registration target

20% (~622) applications cleared by 31 March 2021



### Process target

100% of RW1-3 applications to complete evaluation by Feb 2021

## Variations



10% (~155) of Type II applications finalized by 31 March 2021



# ~65% of expected new registration applications across 11 resubmission windows were received



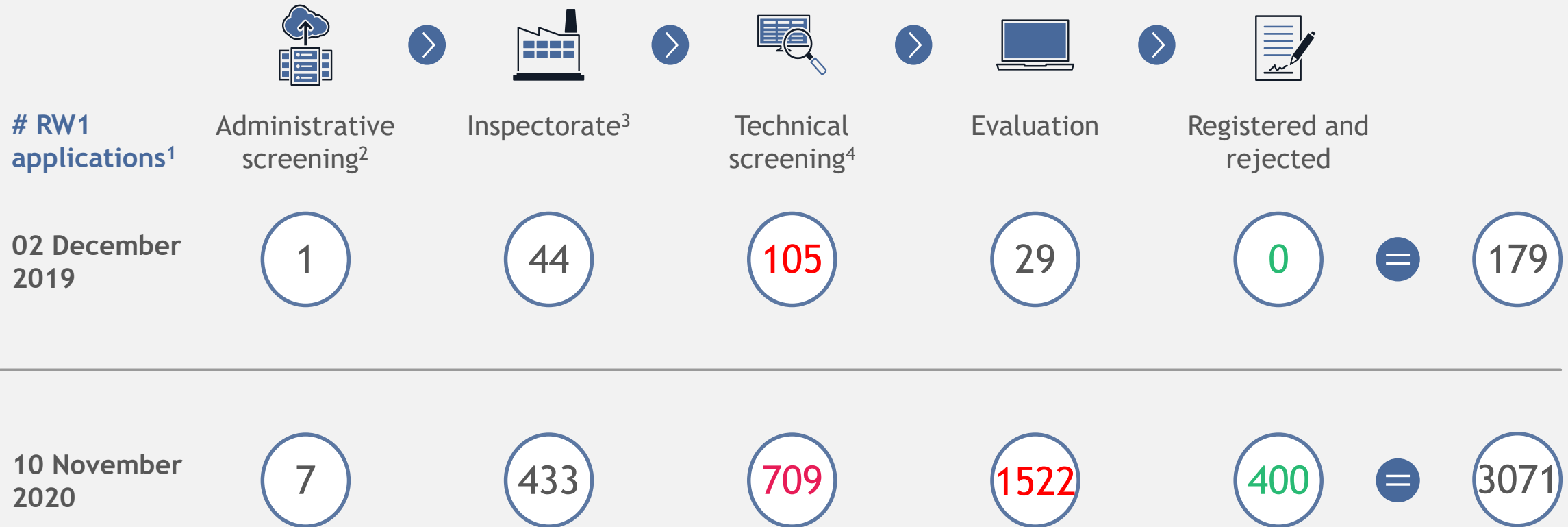
	RW1	RW2	RW3	RW4	RW5	RW6	RW7	RW8	RW9	RW10	RW11	RW12	Total
	Aug - Sept '19	Oct '19	Nov '19	Feb '20	March '20	May '20	June '20	July '20	August '20	Sept '20	Oct '20	Nov '20	-
# of total applications expected <sup>1</sup>	202	526	587	437	245	150	900	496	663	398	183	158	4,946
# of total applications resubmitted	179	416	493	287	157	107	511	321	425	218	95	-	3212
% of expected received	<b>89%</b>	<b>79%</b>	<b>84%</b>	<b>66%</b>	<b>64%</b>	<b>71%</b>	<b>57%</b>	<b>65%</b>	<b>64%</b>	<b>55%</b>	<b>52%</b>	-	<b>65%</b>

RW = resubmission window; 1. Based on Application Survey Database for all remaining 'in' applications, with the assumption that 5% of applications in the backlog are NCEs





# Bulk of applications have advanced to technical screening and evaluation



Note: RW = Resubmission Window

1. Estimated by assuming equal number of total applications per master application; 2. Compliance check & technical validation; 3. Including business validation; 4. Including Names & Scheduling screening & evaluation; 5. Opening date of RW2

# December resubmission window

- ❖ As a result of applicants failure to respond to queries within set timelines, a December 2020 resubmission window was introduced.
- ❖ Requests for extension on **query responses** are no longer processed as applicants are given a chance to submit in December 2020.
- ❖ Applicants now have 20 working days to respond to round 1 screening and evaluation queries, and 5-10 working days for round 2 screening and evaluation queries.

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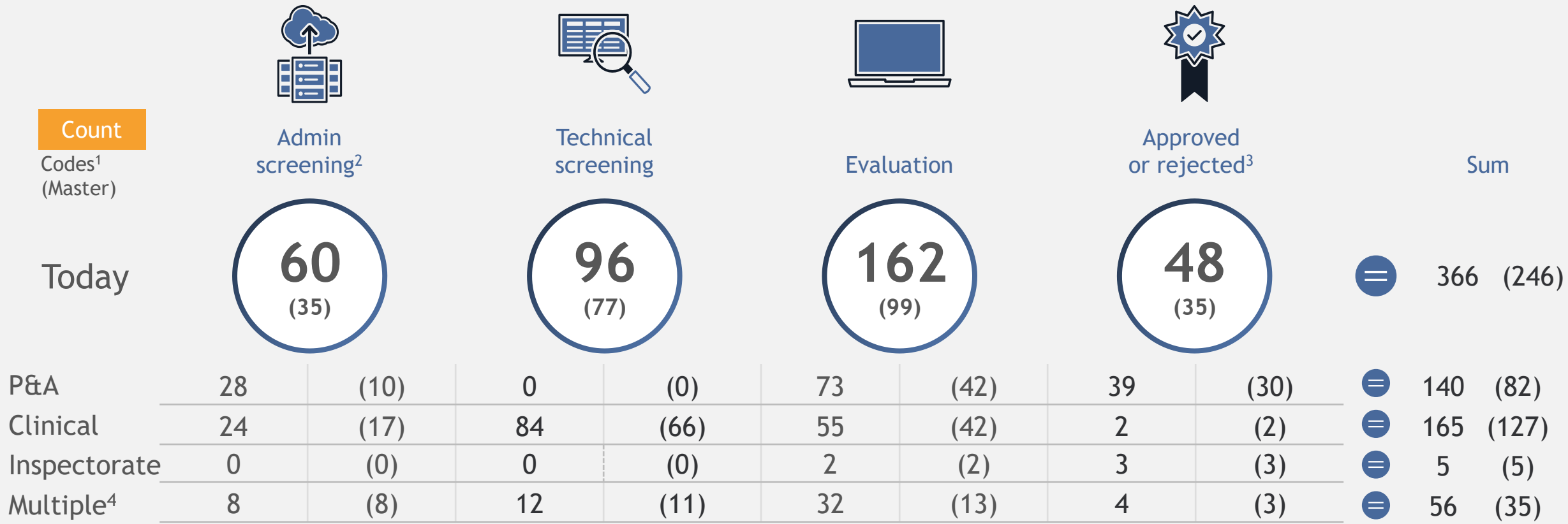
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# Distribution of variations across end-to-end process

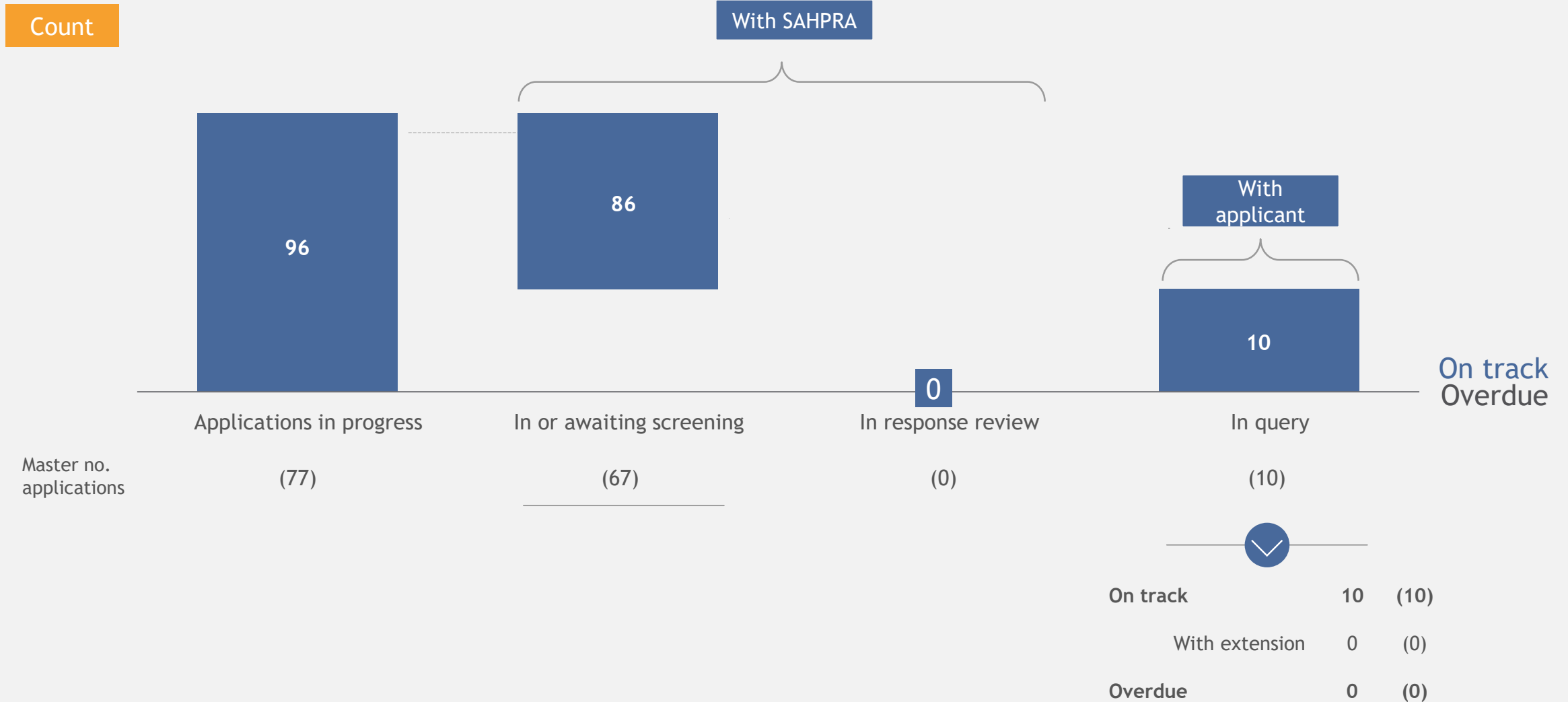
Note: 13% of applications in tech. screening and 37% applications in evaluation are with applicants to address queries



1. Number of type II variation codes associated with the application 2. Compliance check, A.2 technical validation and A.3 business validation; 3. Applications have been approved for registration or rejection by SAHPRA RC. Certificates may not yet be generated and/or issued 4. Applications have a code relevant to multiple units, or multiple codes relevant to multiple units



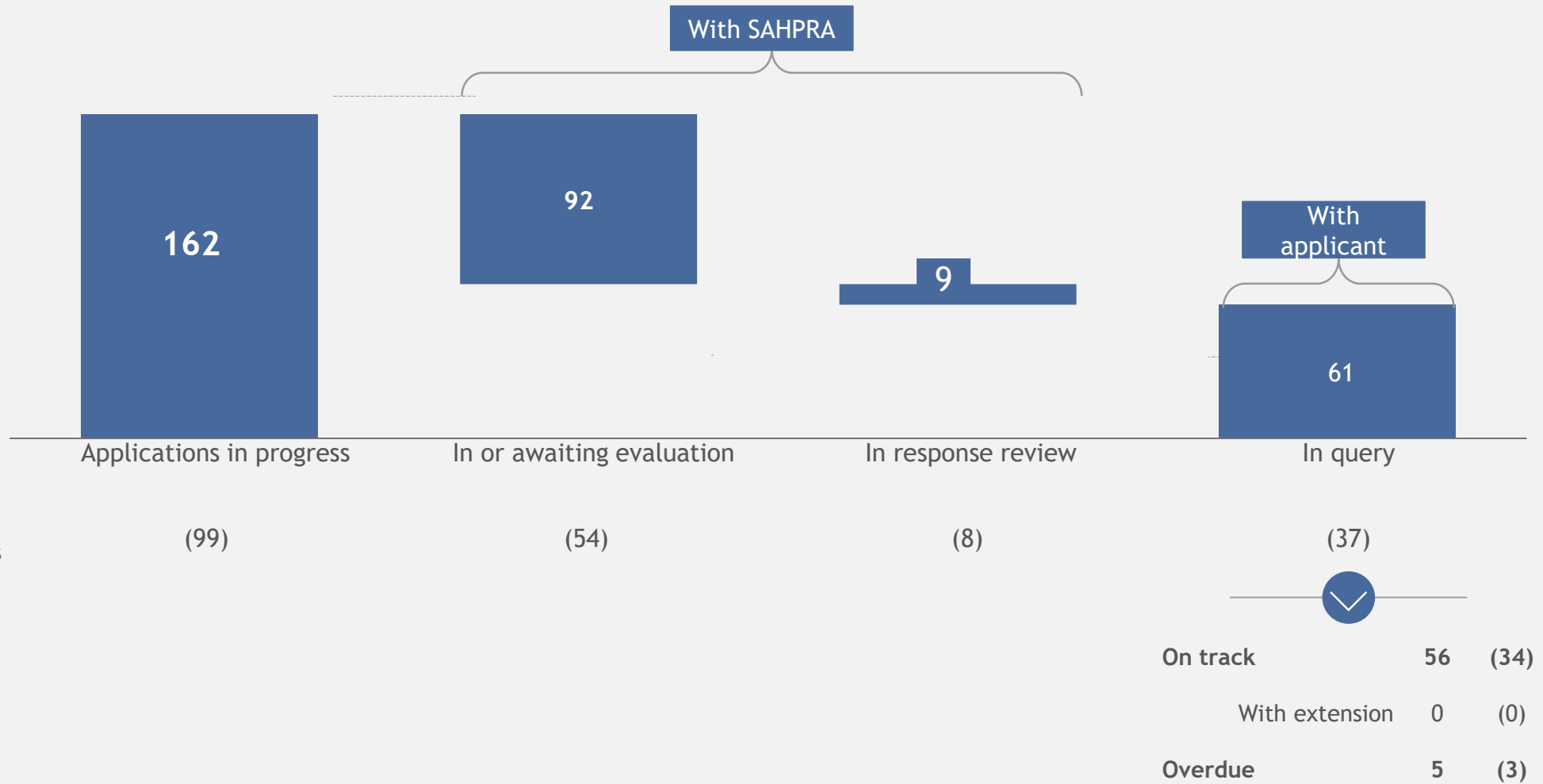
# Variations Deep-dive: Applications in Technical Screening





# Variations Deep-dive: Applications in Evaluation

Count



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# Implementation of Recognition Pathway

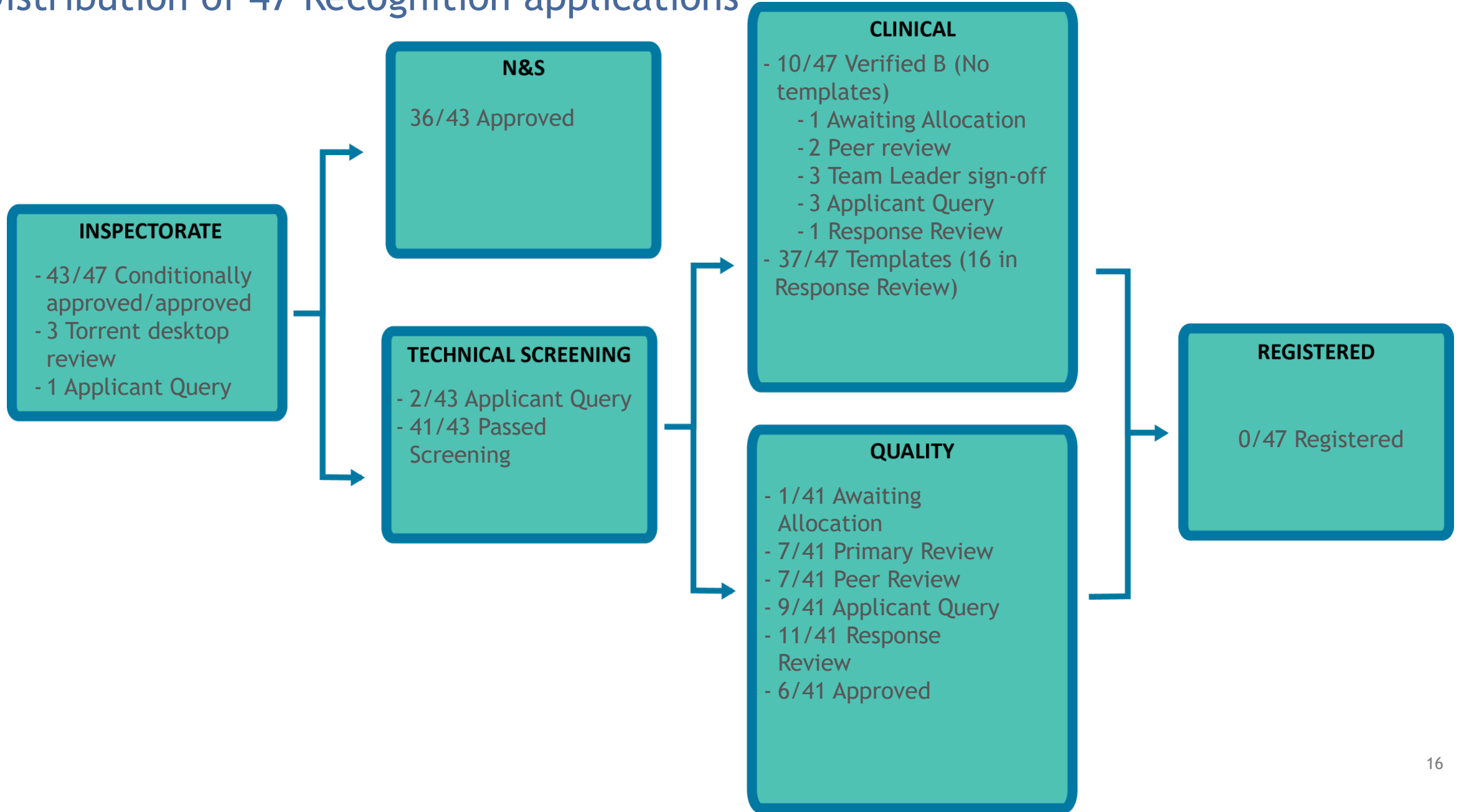
- ❖ 15 applicants have expressed interest in the pilot study, mostly generic (MSM) applicants
- ❖ 56 Masters (~160 line items) submitted by 10 July 2020
- ❖ Withdrawals where marked differences between RRA & proposed ZA dossiers; lack of required information (such as unredacted reports); voluntary withdrawal by applicant
- ❖ To date 47 active applications
- ❖ Initially piloted Recognition; however, Abridged review not optimally implemented
- ❖ Abridged review more relevant, as region-specific data (i.e. FPP stability) to be evaluated
- ❖ First approvals imminent → timeline ~4 - 4.5 months



# Implementation of Recognition Pathway (II/III)

## Distribution of 47 Recognition applications

Update as 13 Nov 2020



# Standardised PI/PIL Templates for RW7

- Completed:
  - Telmisartan
  - Telmisartan & HCTZ
  - Telmisartan & Amlodipine
  - Ezetimibe
  - Ezetimibe & Simvastatin
  - Bisoprolol
  - Rosuvastatin
  - Ivabradine
  - Irbesartan
  - Candesartan
  - Valsartan
  - Valsartan & HCTZ
  - Valsartan & Amlodipine
  - Losartan
- In-Process:
  - Atorvastatin
  - Amlodipine

API	Qty /master applications RPS	Qty/master applications RW7
Telmisartan	10	71
Ezetimibe	6	17
Ivabradine	5	10
Rosuvastatin	4	65
Ezetimibe & Simvastatin	4	22
Bisoprolol	3	22
Candesartan	3	21
Amlodipine & Valsartan	3	47
Irbesartan	2	36
Atorvastatin	1	19
Losartan	1	14
Valsartan	0	57
Amlodipine	0	18

RPS = Recognition Pilot Study

# Challenges with current reliance applications and way forward (I)

Challenges	Proposed solution	Timeline	Impact
<p>Clinical Evaluation is taking longer than anticipated</p>	<ul style="list-style-type: none"> <li>• Deep dive was done to understand the delays in clinical reviews:               <ul style="list-style-type: none"> <li>• NCE Evaluation: Non-alignment with RRA-approved SmPCs (specifically w.r.t 4.3 Contraindications) → Internal Evaluator Guideline drafted and approved to guide reviewers in adopting reliance on prior work done by RRAs</li> <li>• Generic (MSM) Evaluation: Any differences between proposed PI/PIL and ZA Innovator PI evaluated; no reliance on RRA-approved SmPCs → Standardised PI/PILs with additional EU/UK SmPC safety information (RW7)</li> <li>• Workshop to train Clinical evaluators on amended processes/policies - 18 Sep 2020</li> <li>• Lack of experienced Clinical evaluators (shared by BAU &amp; Backlog) → Recruitment of international clinical evaluators</li> </ul> </li> </ul>	<p>July - ongoing</p>	<ul style="list-style-type: none"> <li>• Envisage shortened review timeline</li> <li>• Full impact still to be assessed</li> </ul>

# Challenges with current reliance applications and way forward (II)

Challenges	Proposed solution	Timeline	Impact
<p>Reliance not applied optimally, and time take to evaluate reliance applications is not different to full reviews</p>	<p>Recognition included as reliance pathway and being piloted with RW7 applications.</p> <p>Abridged review applied to these applications to better understand issues underlying the current poor abridged review implementation.</p> <p>Outcomes:</p> <ul style="list-style-type: none"> <li>• <b>Re-engineering of P&amp;A evaluation processes:</b> <ul style="list-style-type: none"> <li>❖ Minimising superfluous templates/reports to be completed by evaluators, especially for abridged/verified review</li> <li>❖ Cutting down on non-value-adding steps within the evaluation process (i.e. minor screening queries → evaluation)</li> <li>❖ Utilising Backlog staff for certain assessments (verified assessments)</li> </ul> </li> <li>• Stricter controls over evaluator deadlines &amp; two additional Evaluators Coordinators to manage this.</li> <li>• Enhanced communication between Backlog and Industry regarding reliance challenges (on both sides)</li> </ul>	<p>July 2020</p>	<ul style="list-style-type: none"> <li>• Envisage shortened review timeline</li> <li>• Full impact still to be assessed</li> </ul>

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