



REGULATORY RATIONALIZATION REVIEW

7TH June 2024

ISSUES

Regulatory Non-Compliance



QUALITY
ISSUES





**WHAT HAS BEEN
DONE**

CLIENT FACING & PRODUCT QUALITY

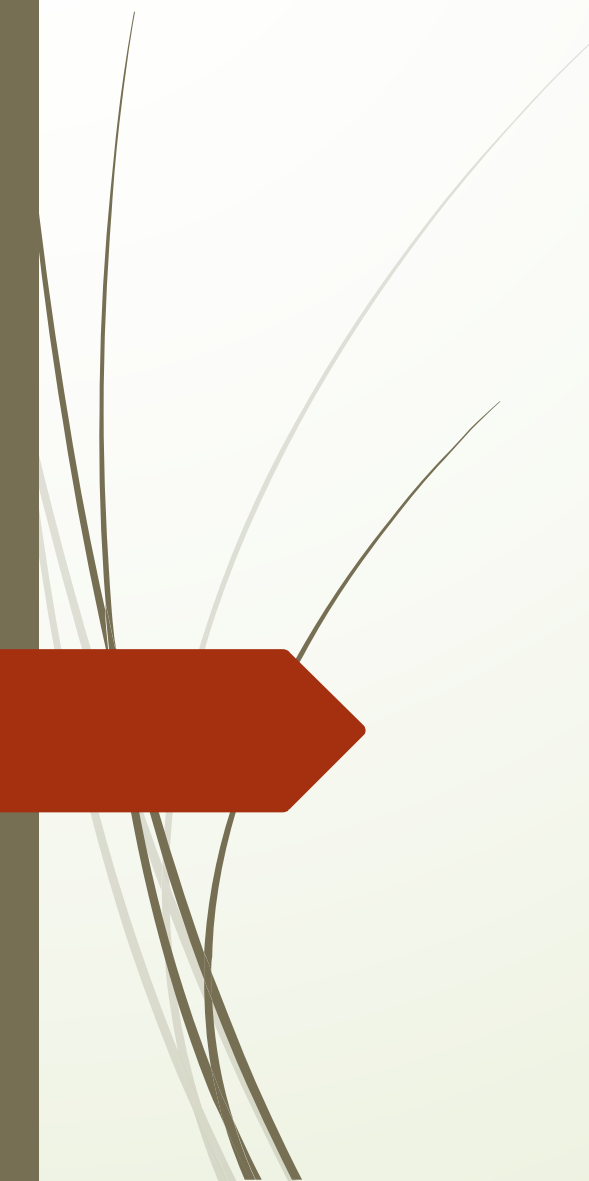
1	Risk Based Inspection ongoing
2	Schedule M Notified on 28 th Dec '23
3	Internation Quality Complains – none significant since July'23
4	Approval of 1 st Car-T Therapy and 1 st SaMD
5	SEC Streamlining - No Deferment since last 6 months
6	Walk-in customer meeting – twice a week, started from Feb'24. around 90 issue resolved
7	Increased Digitization – Blood Bank, Post Approval Changes, Market sampling and downstream activities, Online CDSCO Testing Labs, Export NoC etc.
8	Enhanced Technical Scrutiny, On site data review

INTERNAL PROCESSES AND PRACTICES

- | | |
|---|--|
| 1 | 207 Transfers of staff for the 1 st time in history of CDSCO |
| 2 | CDSCO initiated Departmental enquiry for malpractices in CDSCO |
| 3 | Termination / transfer of employees for malpractices |
| 4 | Initiation of internal quality audit – currently various parts are being covered |
| 5 | Structured Capacity Building exercise at NIHFW |
| 6 | Monthly meetings with State Drugs Control |
| 7 | Digital Dashboard for File Pendency – focused intervention |
| 8 | Access control at CDSCO |

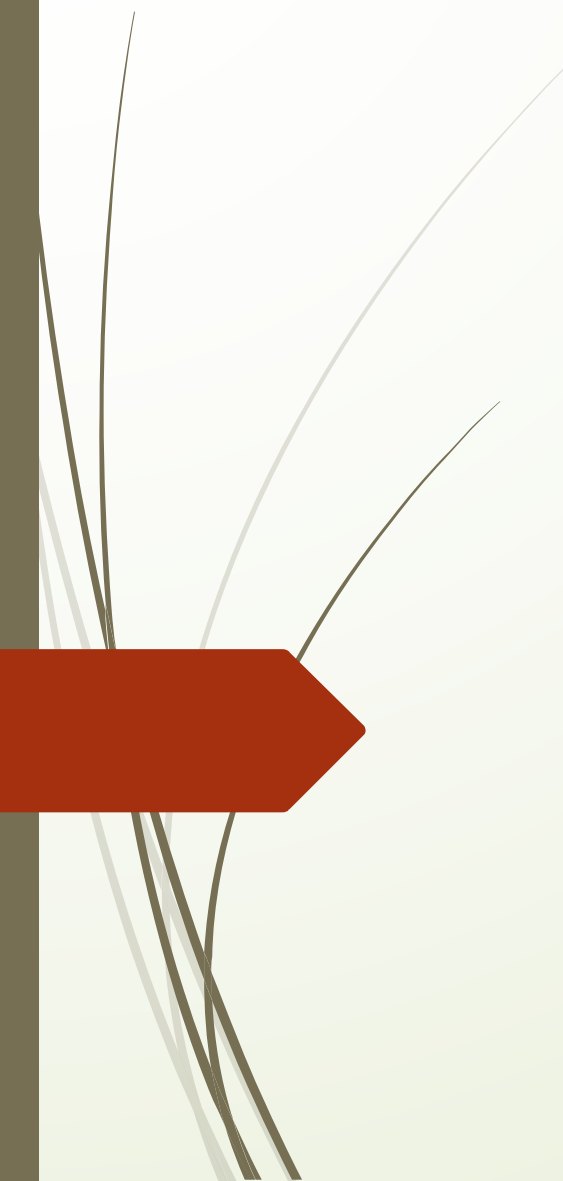


WHAT IS COMING



4 BIG TICKET PROJECTS IN PIPELINE

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1	DIGITAL DRUG REGULATORY SYSTEM (DDRS)
2	DRUG REGULATORY RATIONALIZATION INITIATIVE
3	INTERNAL SCIENTIFIC CADRE AT CDSCO
4	DIGITAL IP



1	SEC WORKING GUIDANCE
2	EXPORT LICENCE RATIONALIZATION
3	REDUCTION IN TOX REQUIREMENT
4	HARMONIZED DIGITAL WHO COPP
5	HARMONIZED CT SITE/INVESTIGATOR ADDITON PROCESS
6	USE OF AI INTERVENTION IN REGULATORY VALUE CHAIN
7	DISCOVERY RESEARCH REGULATION RATIONALIZATION

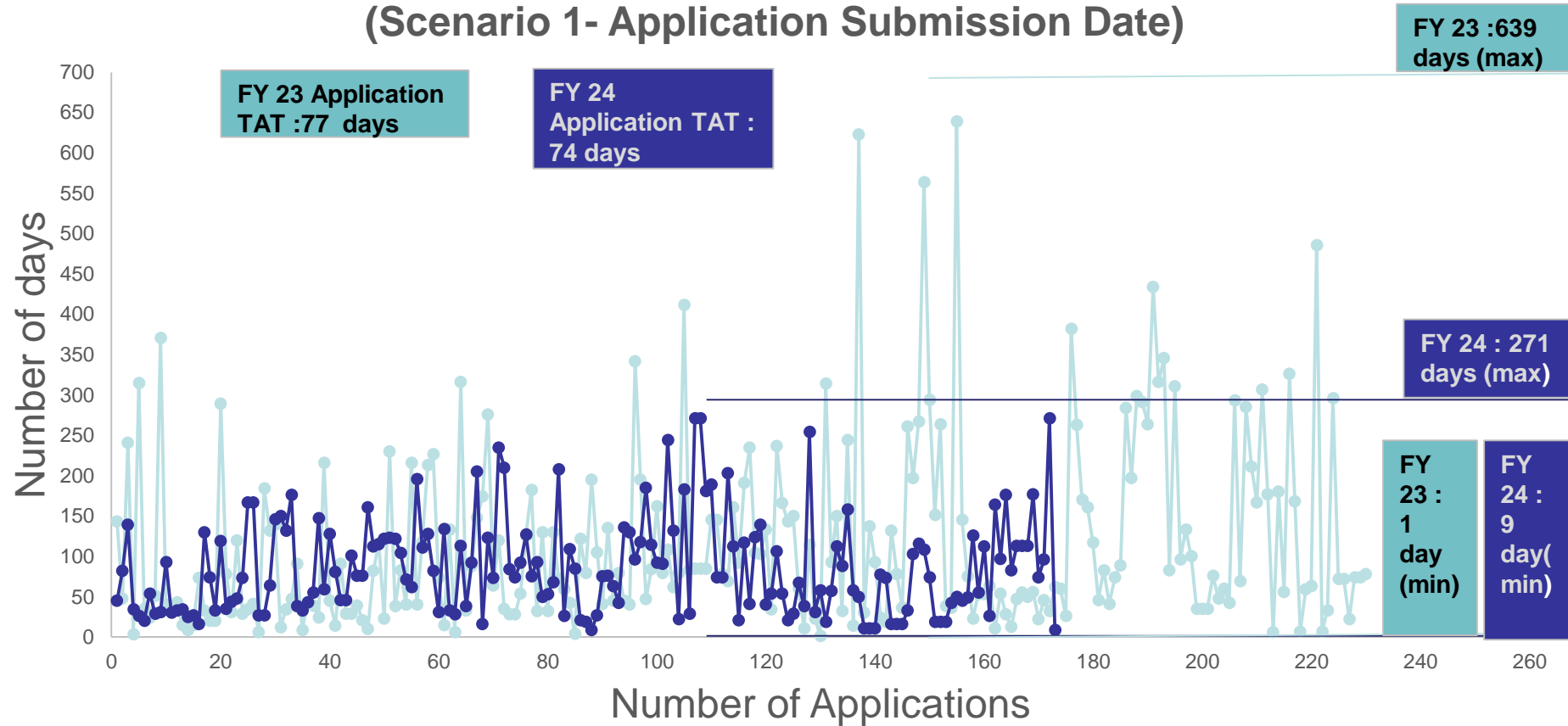
EXPORT NOC - APPROVAL STATISTICS

1	Total Number of Applications Received since 15 th May'24	476
2	Number of Applications Approved	314
3	Number of Applications Approved without query	287
4	Average No. of Days to Approval	3.2
5	Average No. of Days to Approval with Query	7.3
6	Average No. of Days to Approval without Query	1.7
7	Number of Applications with applicant – query raised	39
8	Number of Applications in process at CDSCO	14

Approval Timelines



Vaccines : Approval time line vs Number of Application (Scenario 1- Application Submission Date)

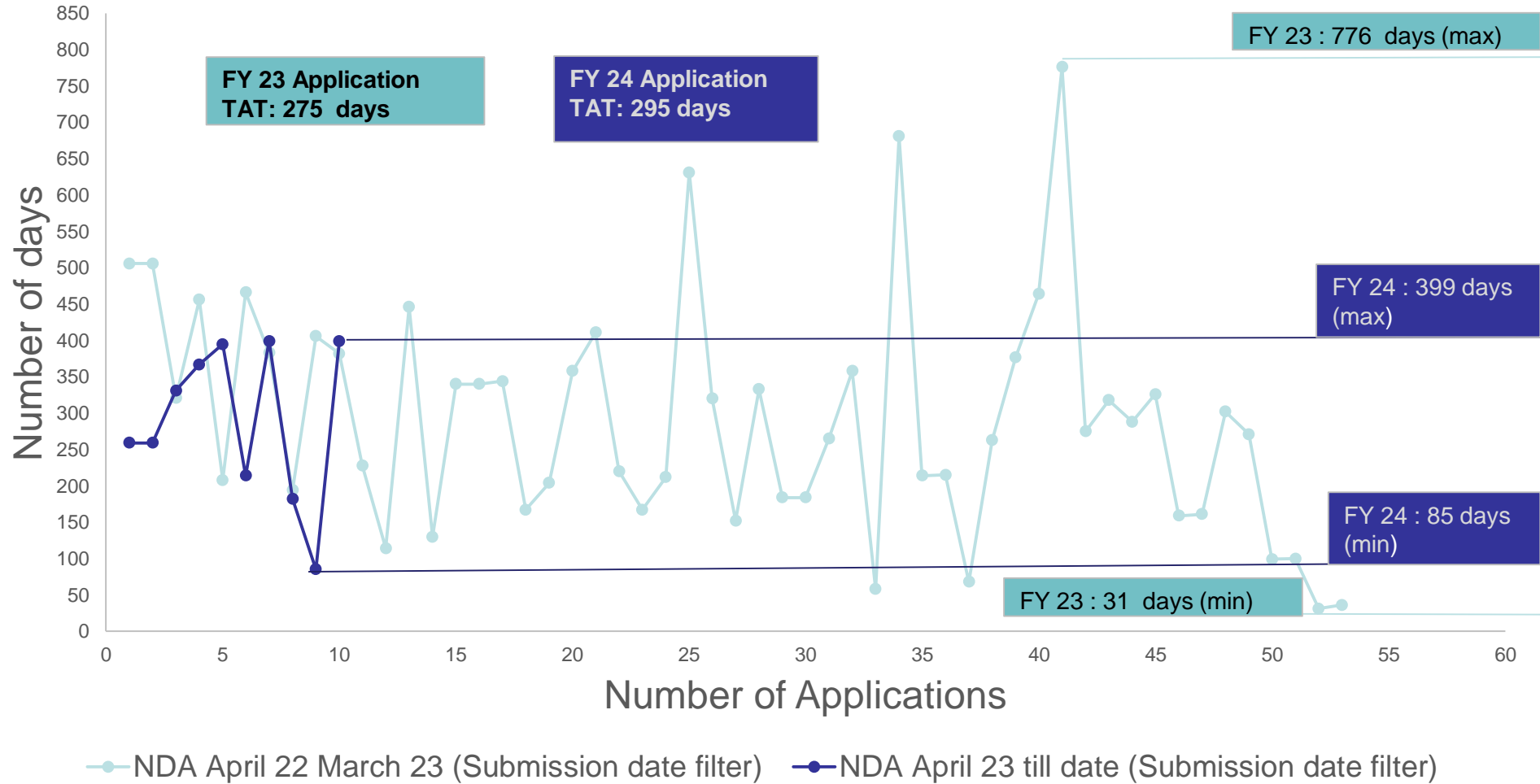


- Vaccine April 22 March 23 (Submission date filter)
- Vaccines April 23 till date (Submission date filter)

TAT (Turn around time) : Calculated based on median



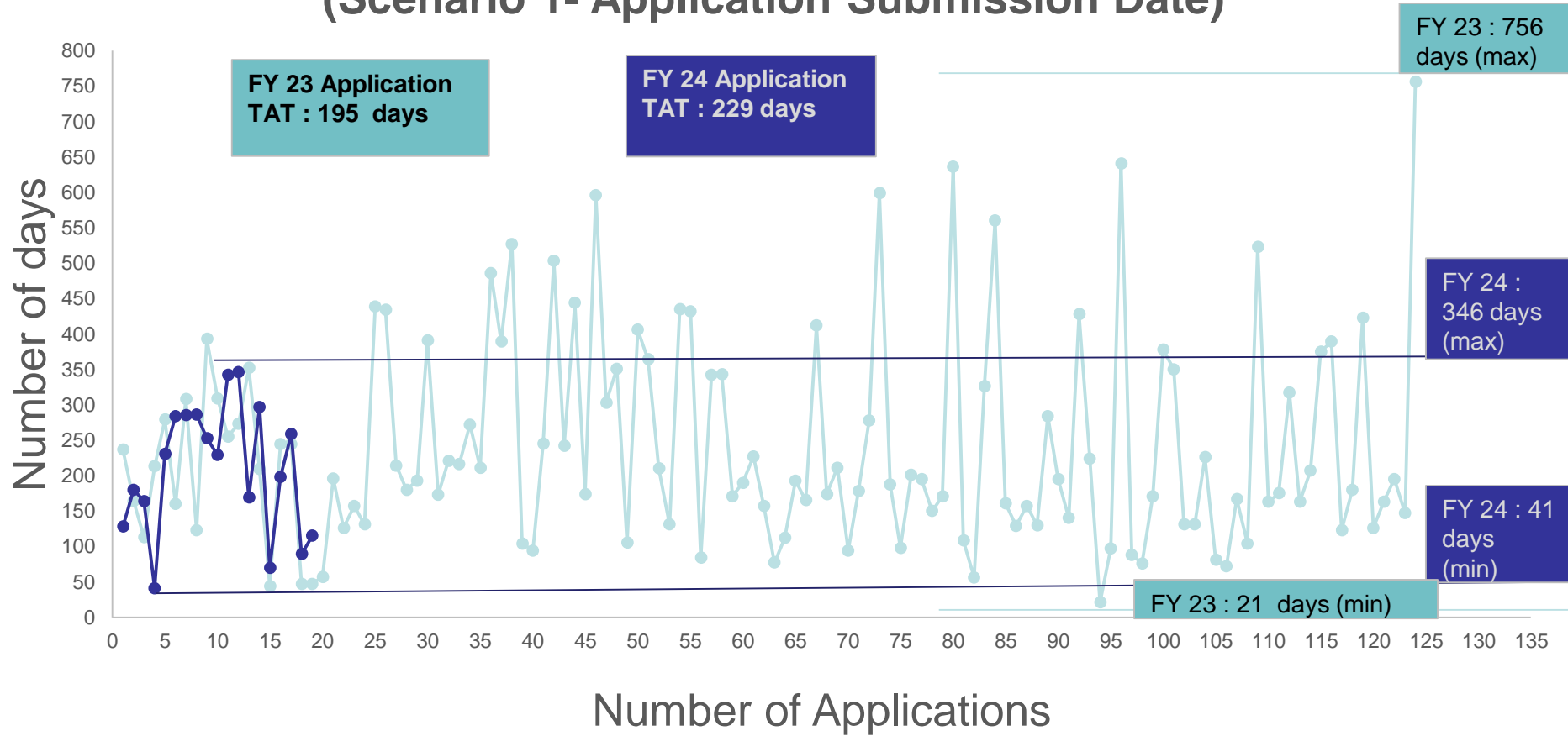
NDA : Approval time line vs Number of Application (Scenario 1- Application Submission Date)



TAT (Turn around time) : Calculated based on median



SND : Approval time line vs Number of Applications (Scenario 1- Application Submission Date)

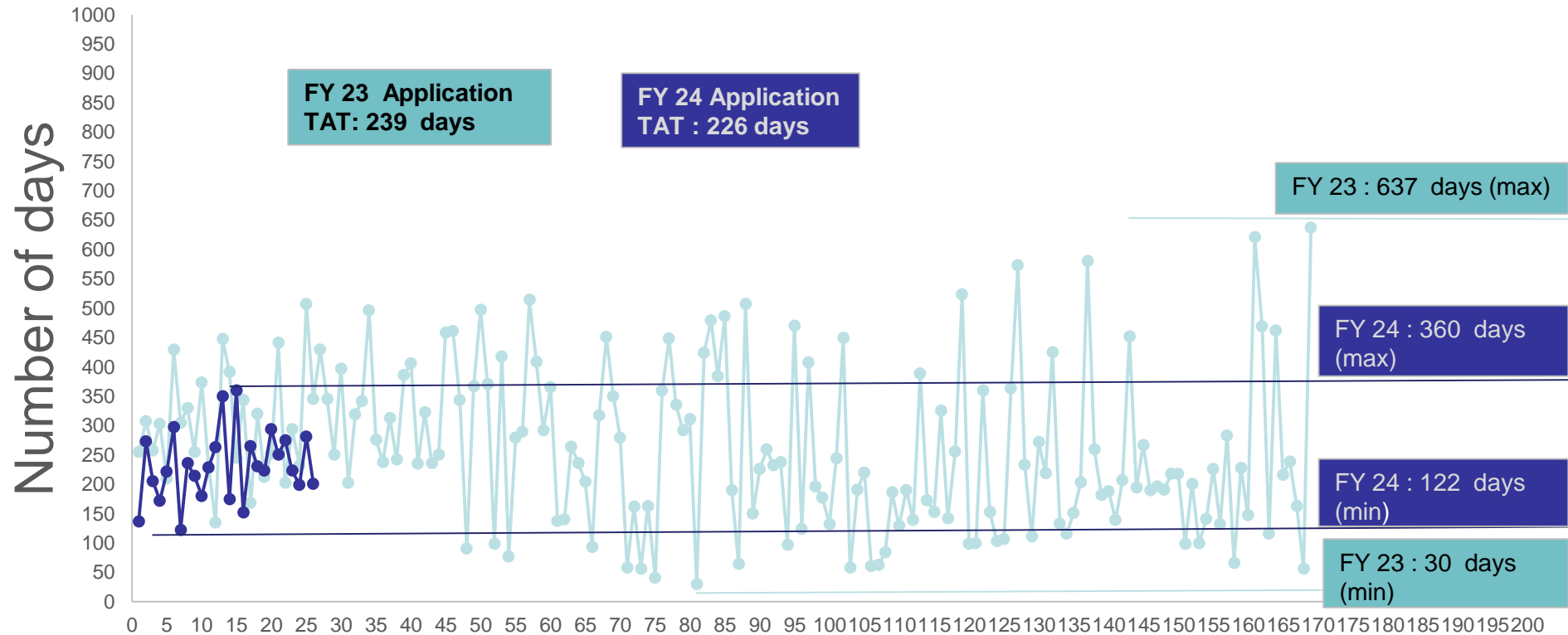


—●— SND April 22 March 23 (Submission date filter) —●— SND April 23 till date (Submission date filter)

TAT (Turn around time) : Calculated based on median



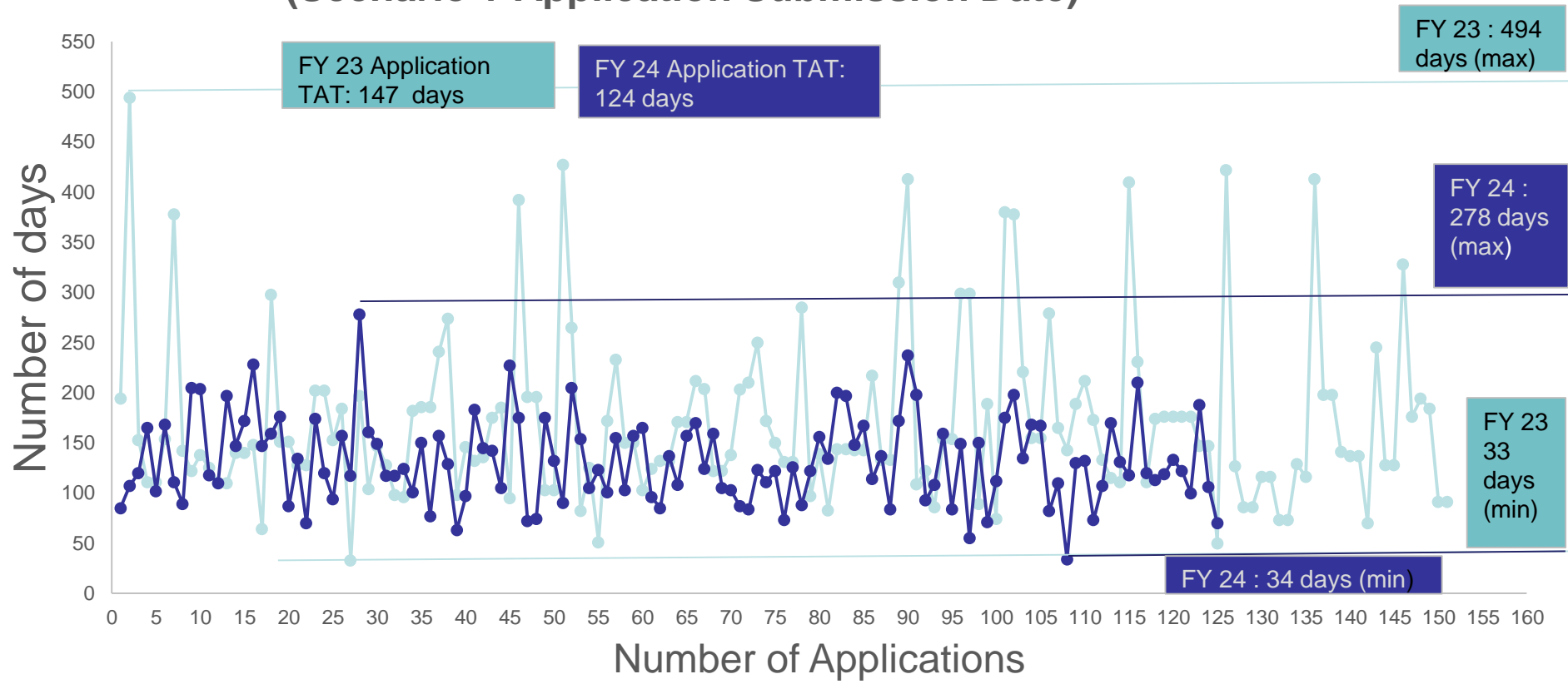
FDC : Approval time line vs Number of Applications (Scenario 1- Application Submission Date)



— FDC April 22 March 23 (Submission date filter) — FDC April 23 till date (Submission date filter)

TAT (Turn around time) : Calculated based on median

GCT :Approval time line vs Number of Application (Scenario 1-Application Submission Date)

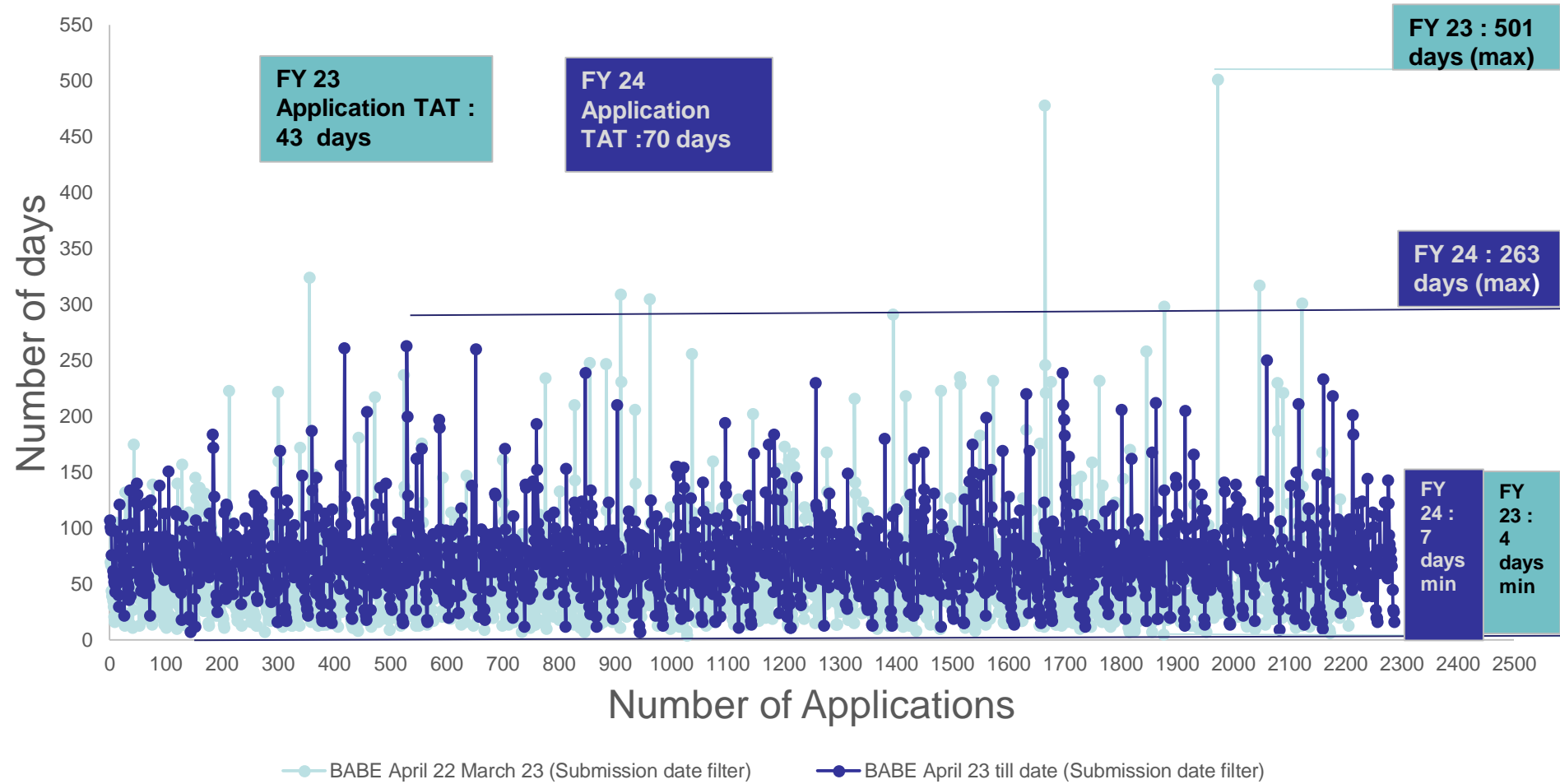


—●— GCT April 22 March 23 (Submission date filter) —●— GCT April 23 till date (Submission date filter)

TAT (Turn around time) : Calculated based on median



BABE : Approval time line vs Number of Application (Scenario 1-Application Submission Date)

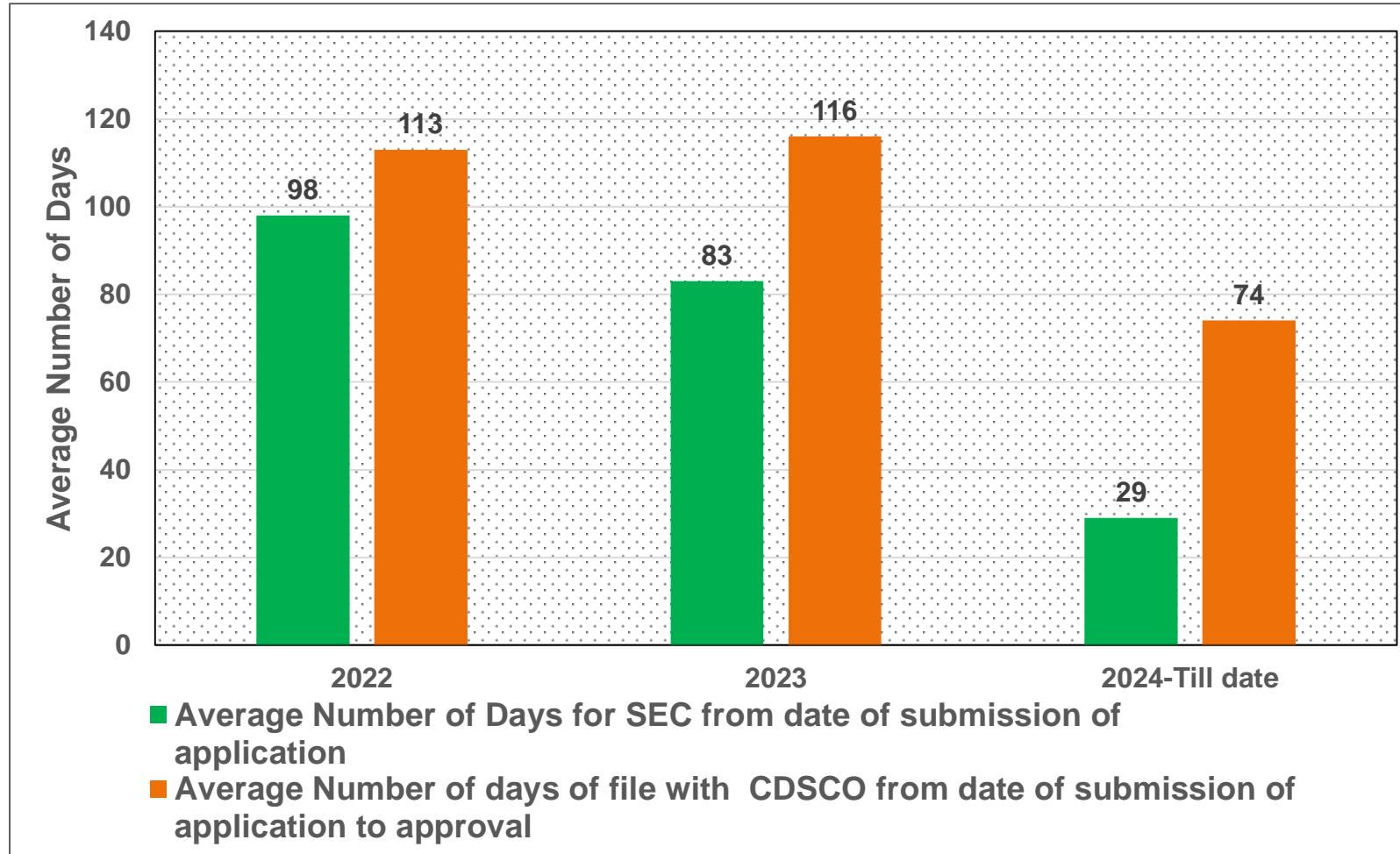


TAT (Turn around time) : Calculated based on median



Statistics of Timeline of GCT Applications (CT-04)

Average No. of Days

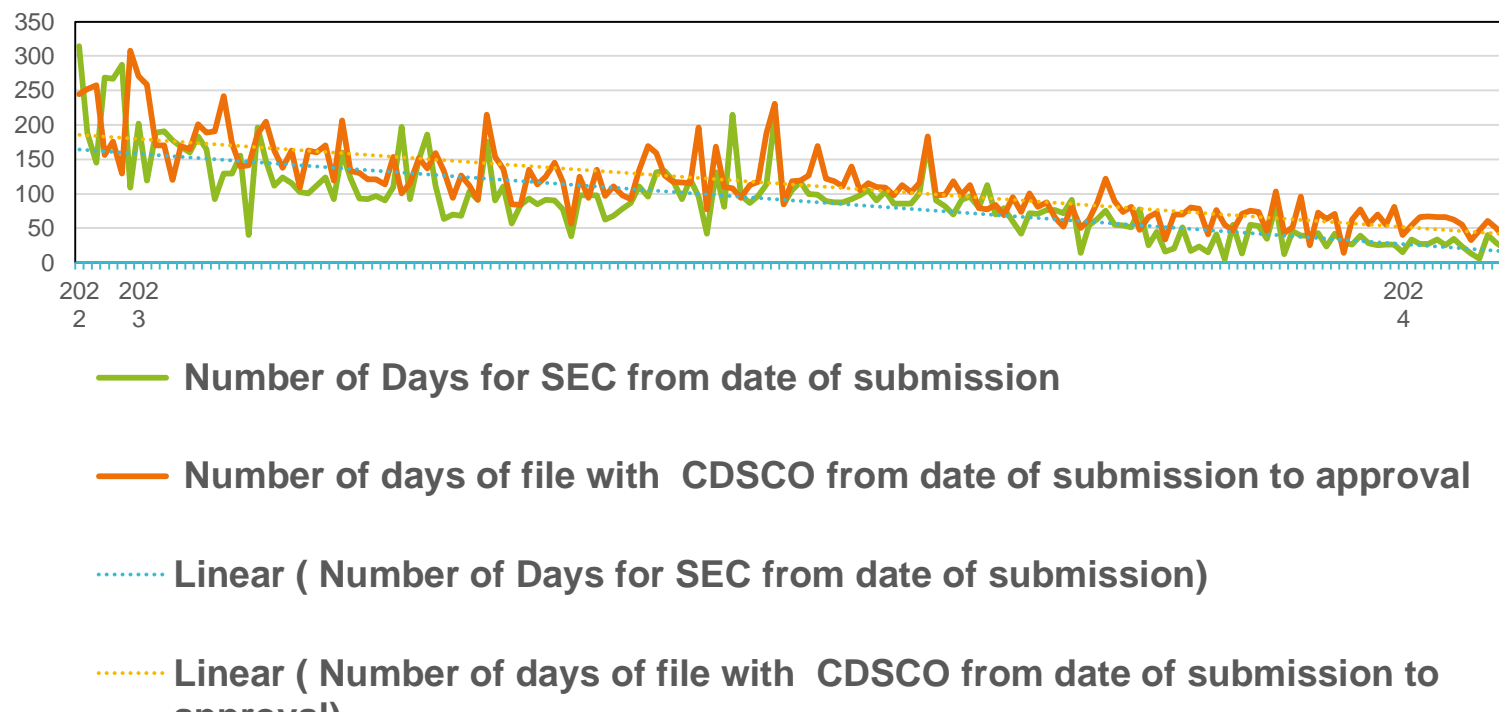




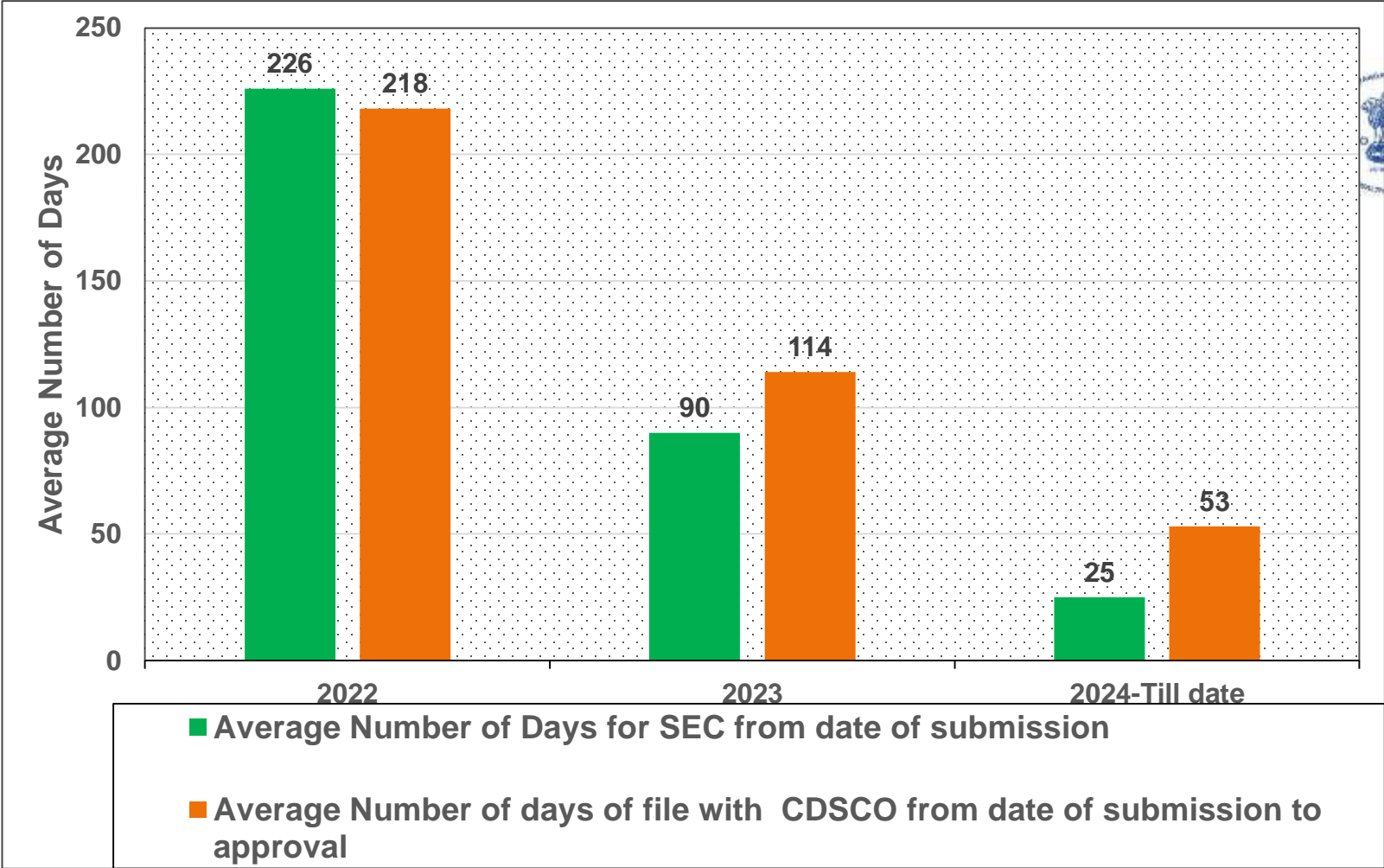
Statistics of Timeline of GCT Applications (Post Approval Applications-Major)



Trend of SEC Deliberation and approval time for Major Post Approval applications in GCT Division



Average No. of Days



No of companies

Absence of deep thinking in reg/qual

No of products

Where are we faltering

Skill deficit

Cost Vs quality

Will deficit

Regulatory structure



THANK YOU

