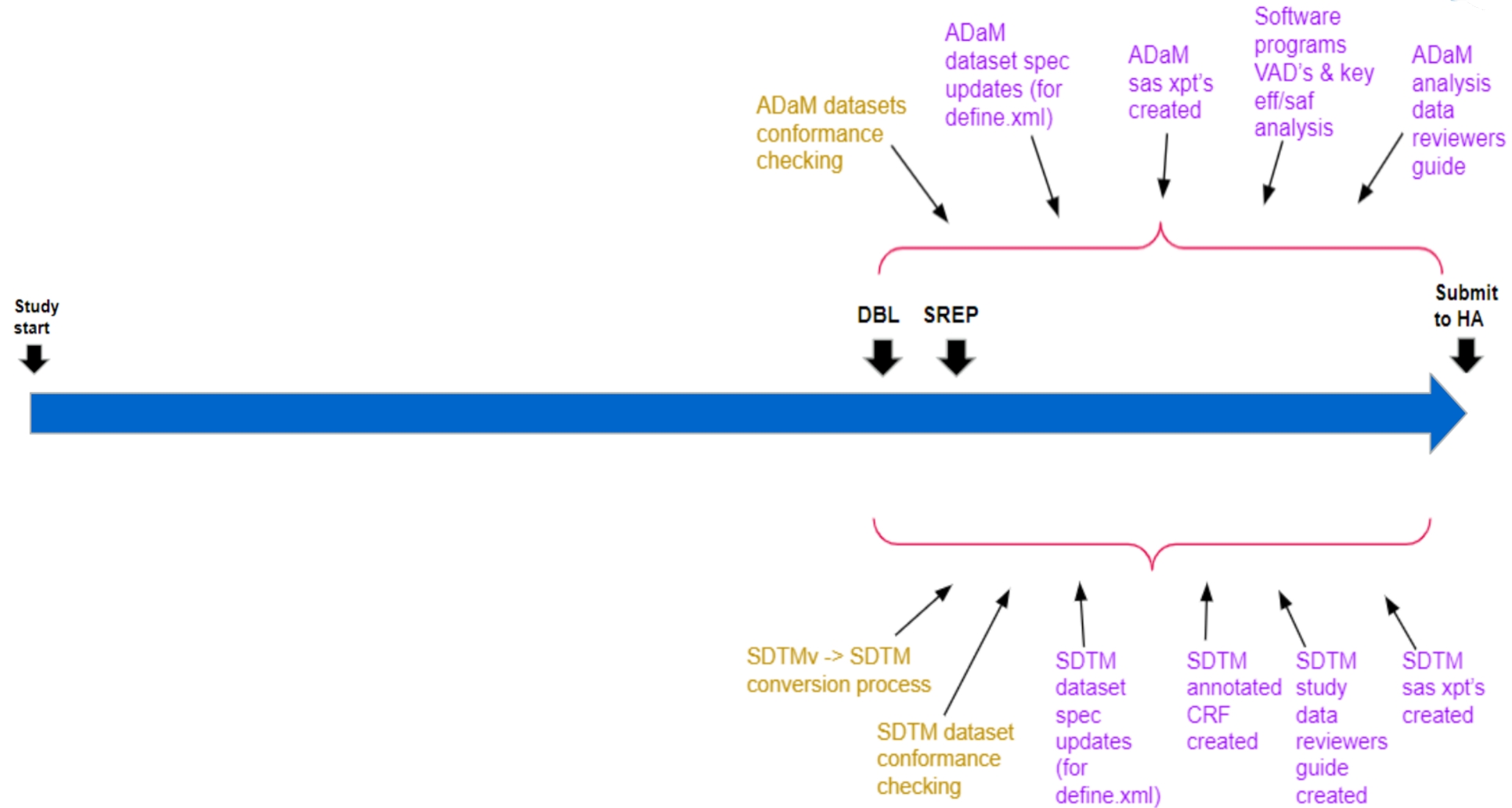

Presentation No – SA08
Title: F³: Fitness, FAIR and Filing
PHUSE EU CONNECT Nov 2021

Nigel Montgomery & Bhupendra Mistry
Roche - Genentech

Agenda:

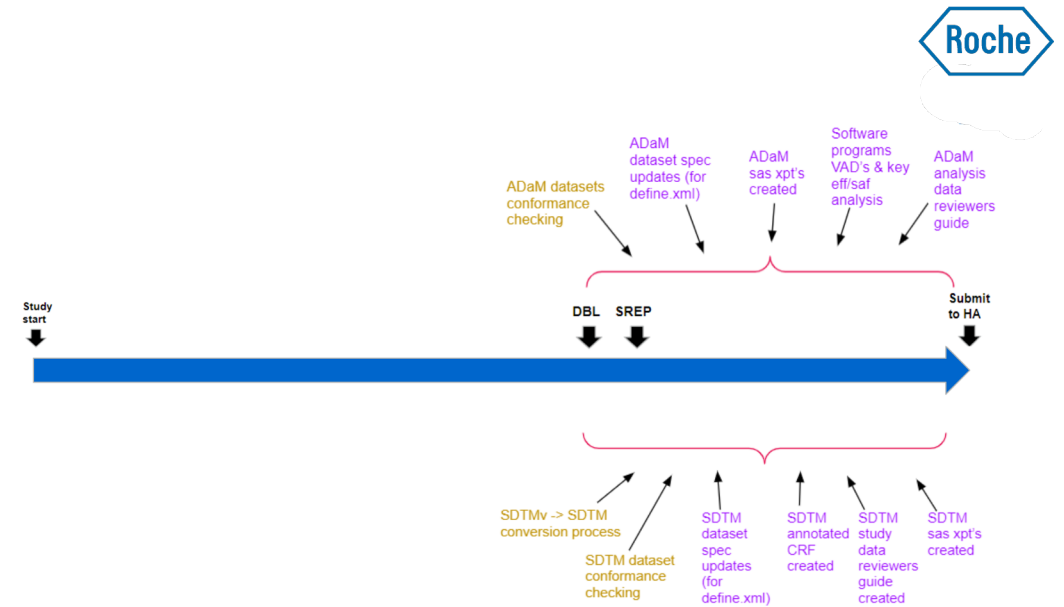
- **Current State (& Desired)**
- **Pro-active approach / Change in mindset**
- **Tools & Guidance's**
- **Readiness Checklist**
- **Readiness Dashboard**
- **Desired State**
- **Summary**

Current state:



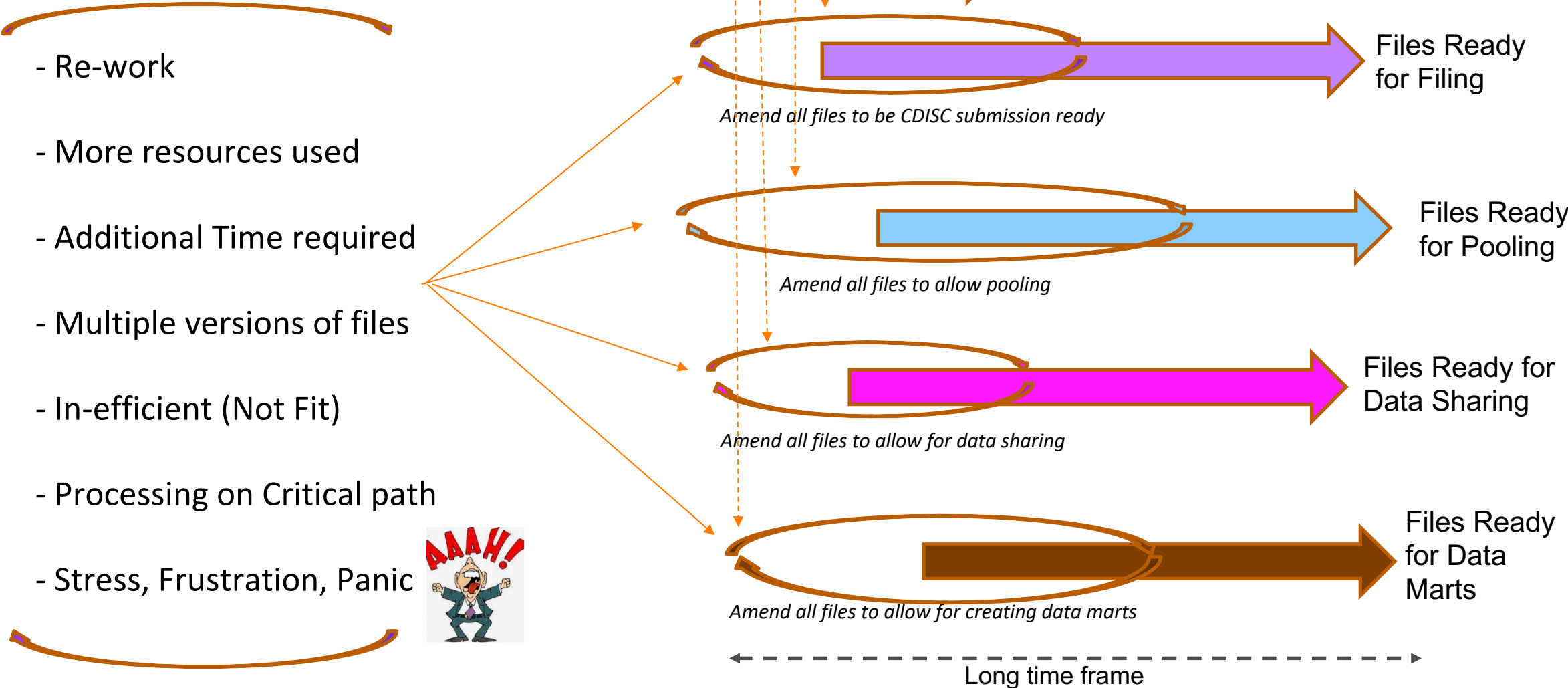
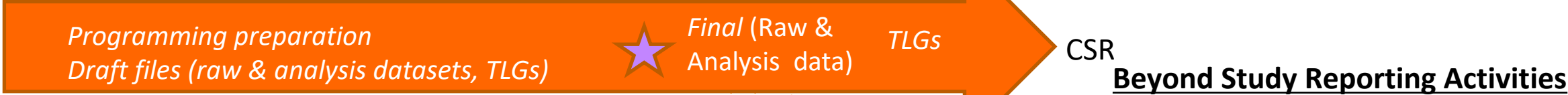
Current state

- Programming focus primarily of CSR deliverables
- Standards used but not maintained
- Metadata maintenance is suboptimal
- Lack of future use in mind, re-active approach instead of pro-active
- Negative impact on resources, time and re-work – unsustainable
- Change in mindset required to be F.A.I.R. as general practice



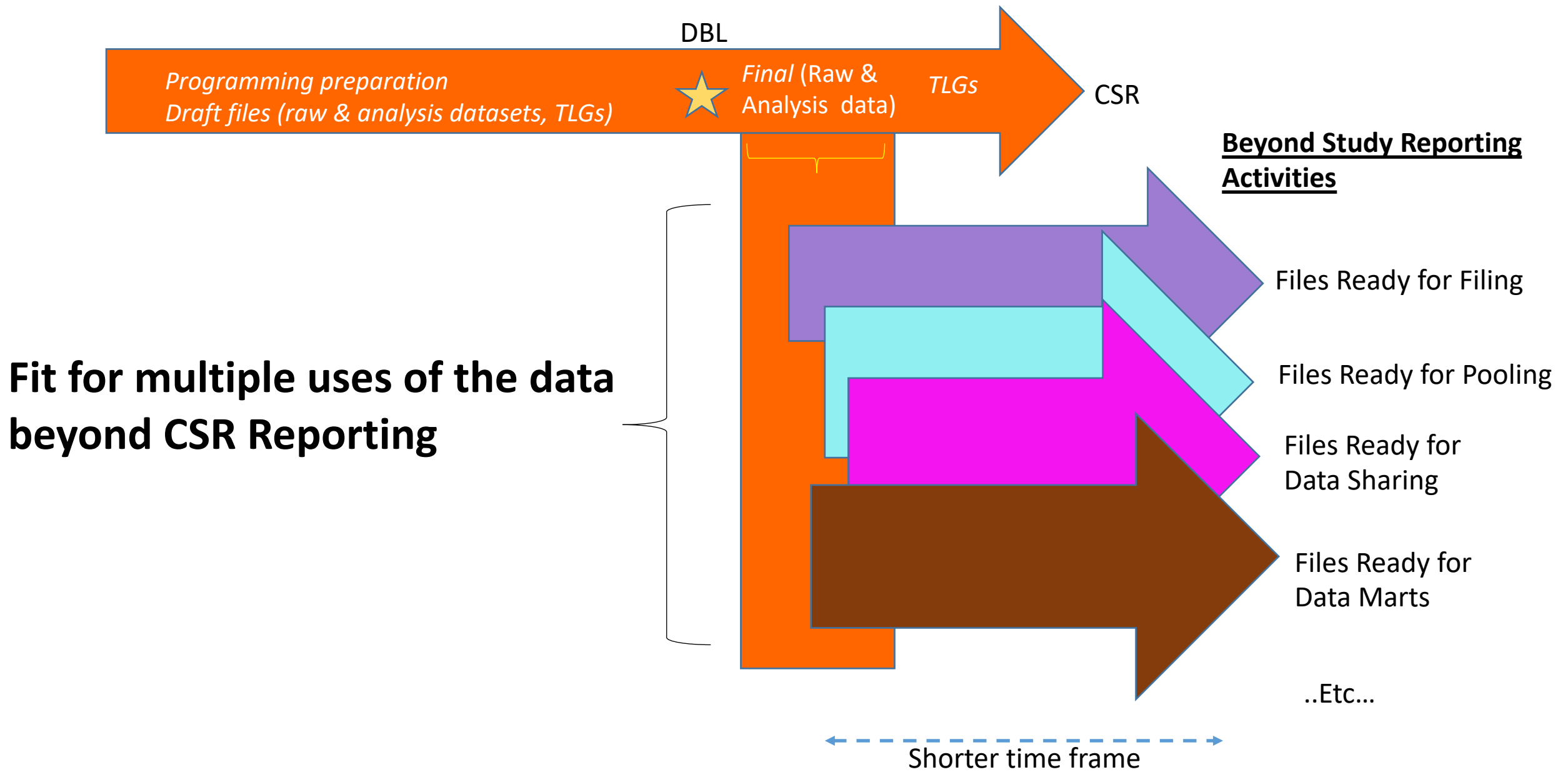
Study Level reporting

Current State

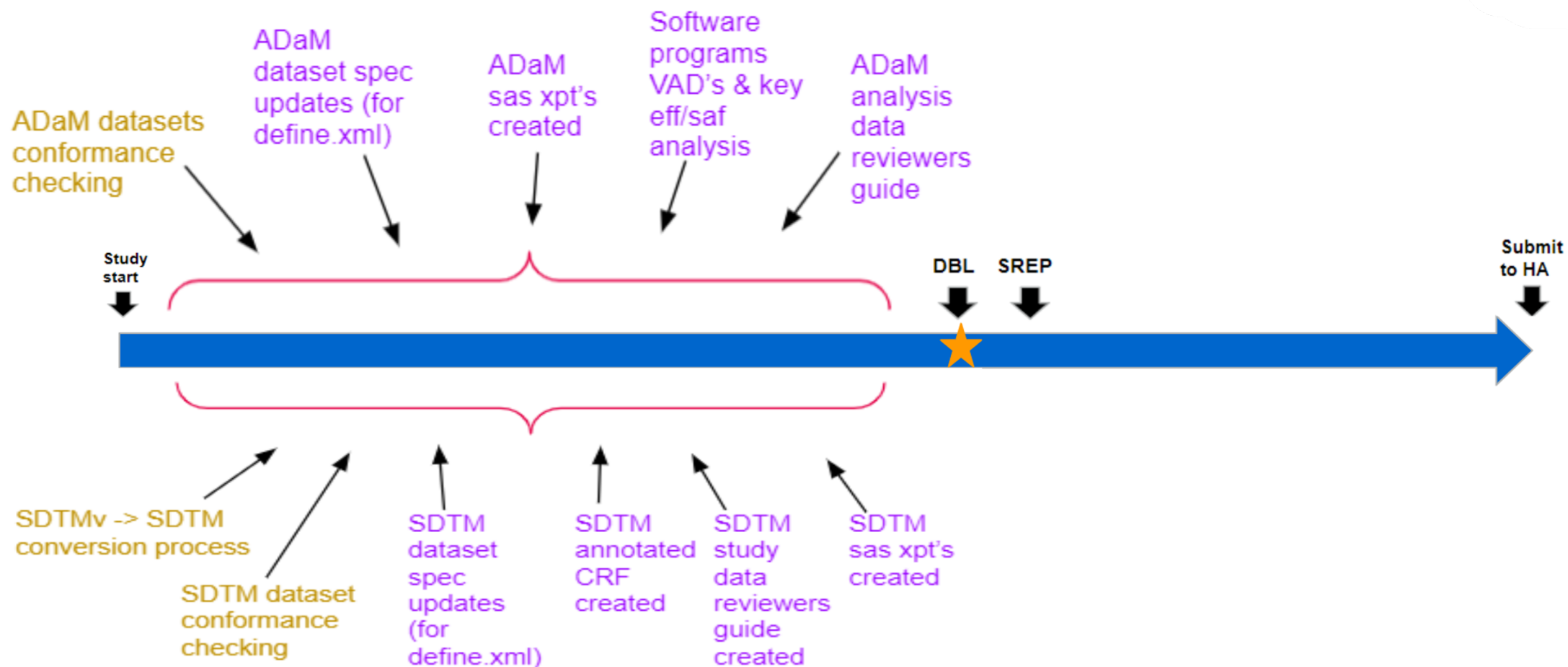


Study Level reporting

Desired State



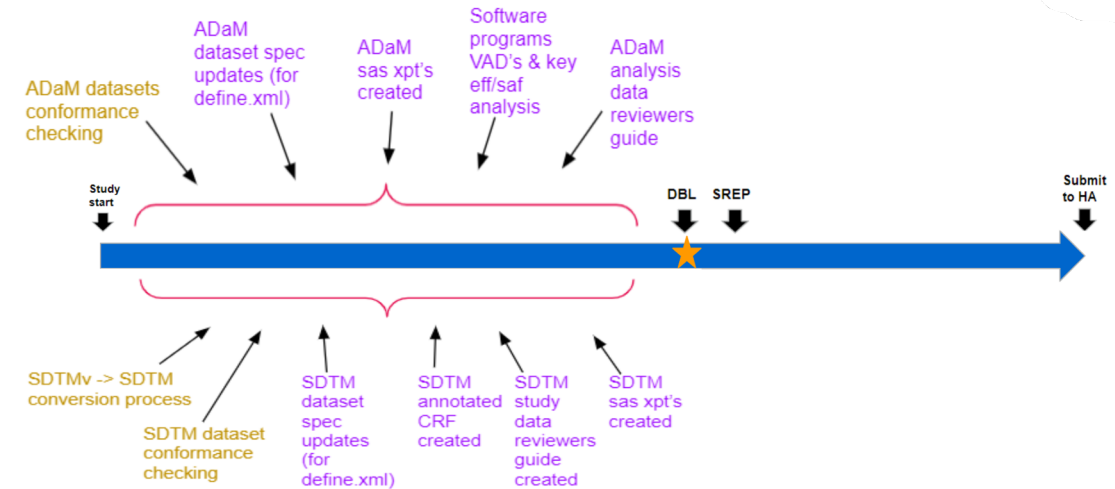
Pro-active approach / Change in mindset



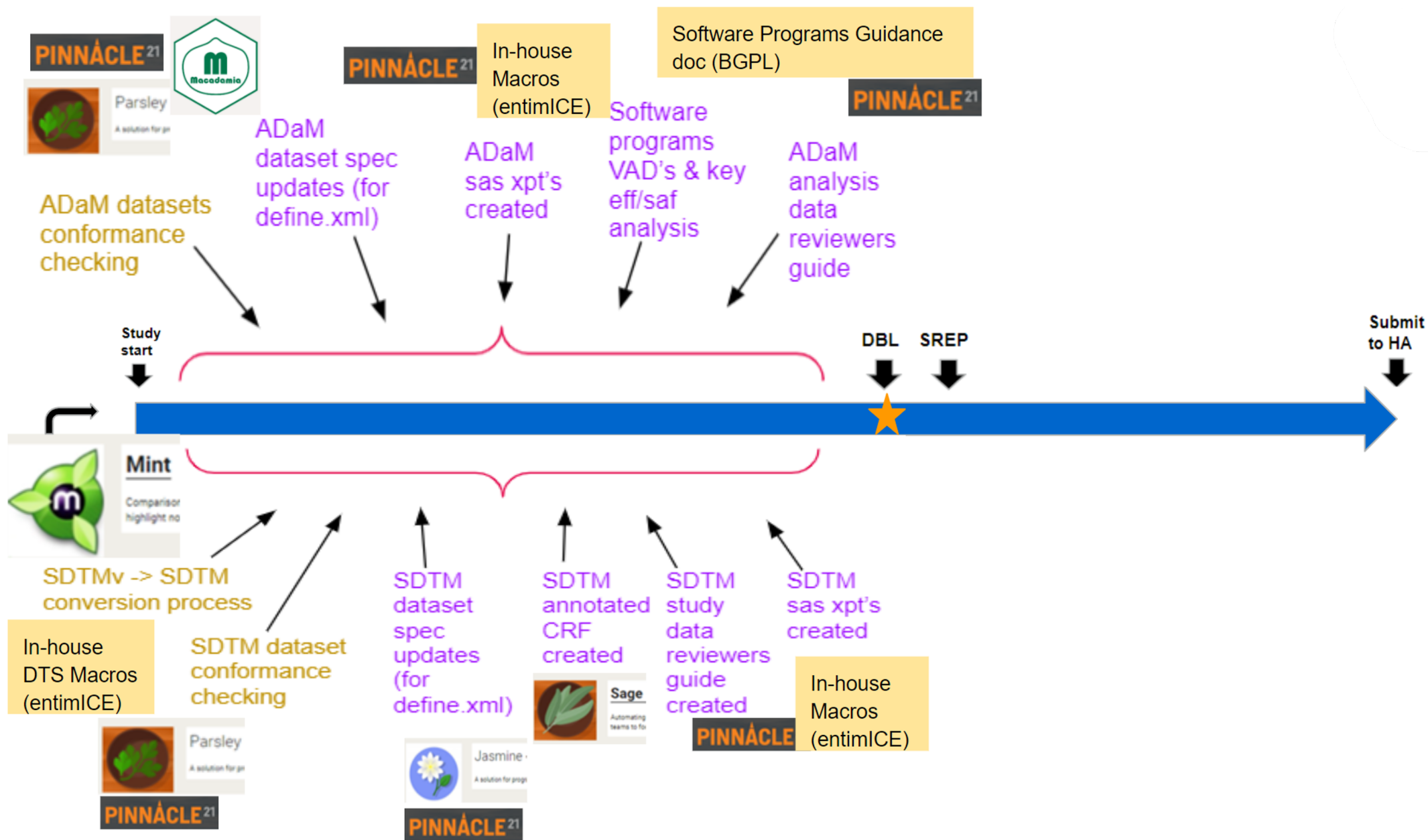
Pro-active approach / Change in mindset described



- From re-active to pro-active (longer term gain)
- Reduce downstream re-work, panic, time
- Change in mindset - adopting a submission approach (the gold standard) regardless of filings
- Consistent approach across molecules and teams
- greater opportunities for tools development and automation



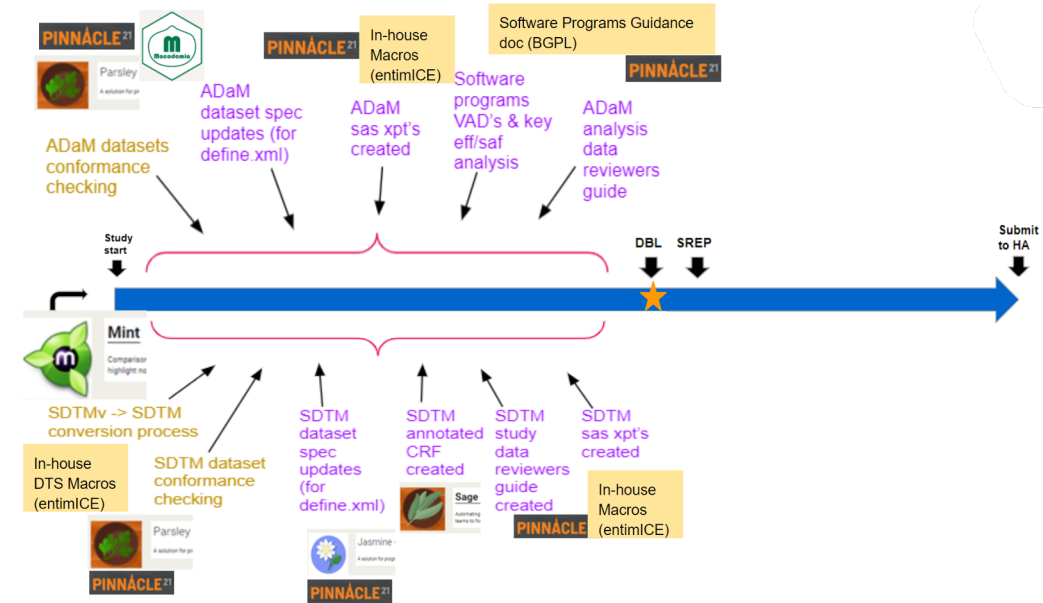
Tools & Guidance's



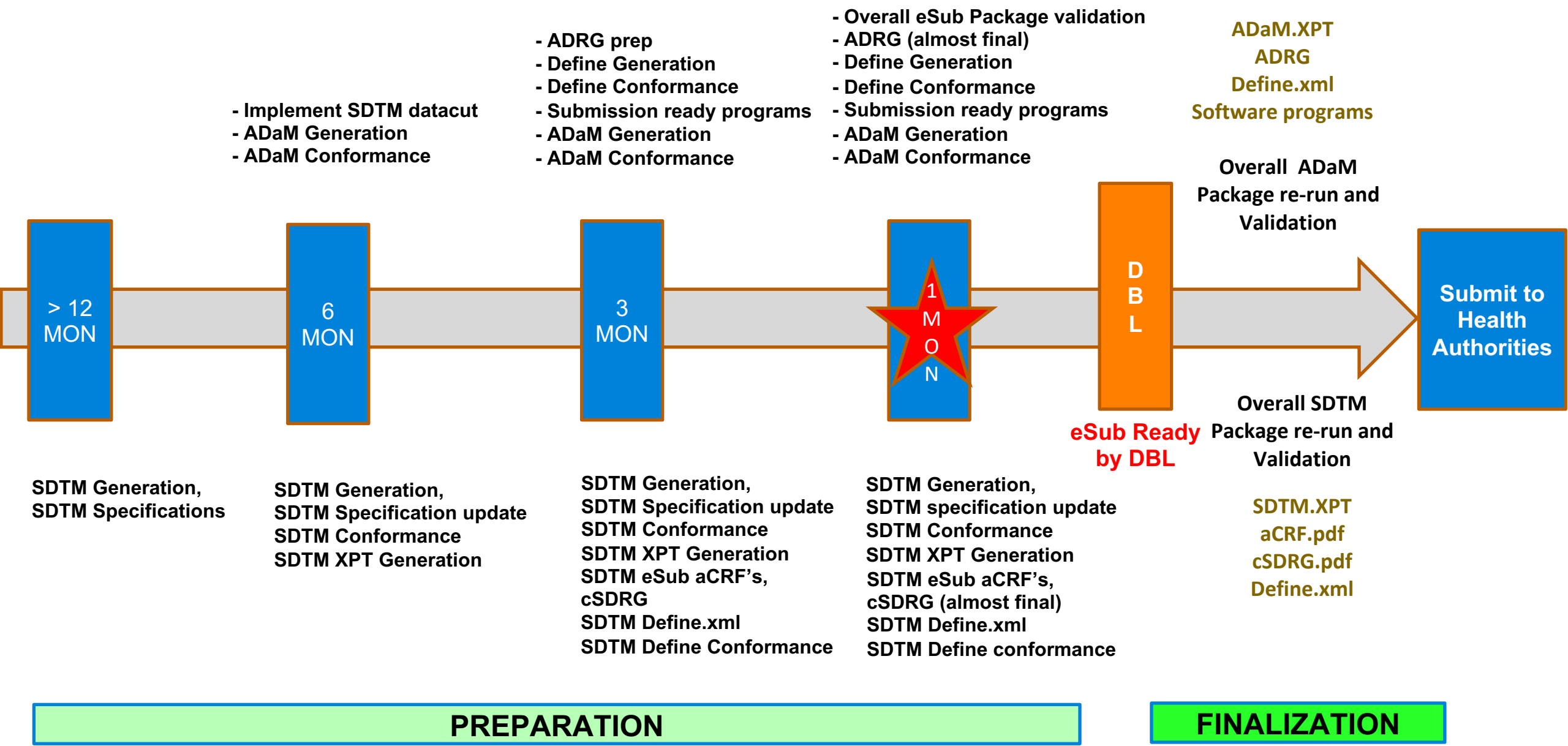
Tools & Guidance's



- In-house tools
 - aCRF generator (MINT & SAGE)
 - Specification checkers (JASMINE & MACADAMIA)
 - Global Standards (GDSR) adherence (MINT)
 - API & CLI to connect and execute applications (PARSLEY)
 - Macros
- Internal guidance's i.e. Submission of software programs
- Provide support and guidance in the use of off-the-shelf tool
- Impact :
 - Time reduction in aCRF creation by ~75%
 - Automated Specification checks removes manual review, can save >5 days
 - Automated conformance execution, can save ~30mins per conformance run



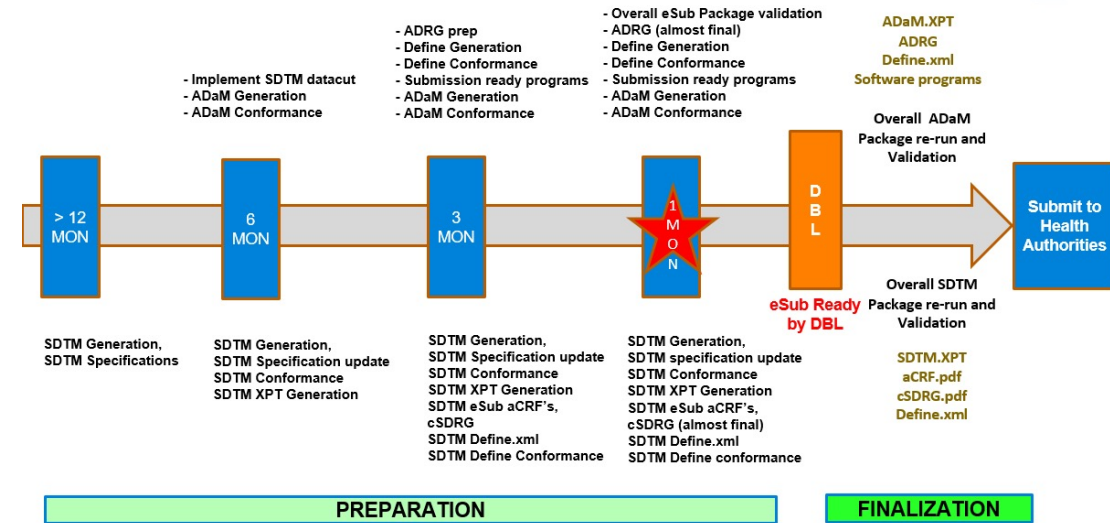
Readiness Checklist



Readiness Checklist

- Checklist is a step-by-step guidance
- Recommended timings and timeframes of when tasks should be done
- Order of execution and identifies dependencies
- Recommendations and use of best practices.
- Aiming to be >90% ready by DBL

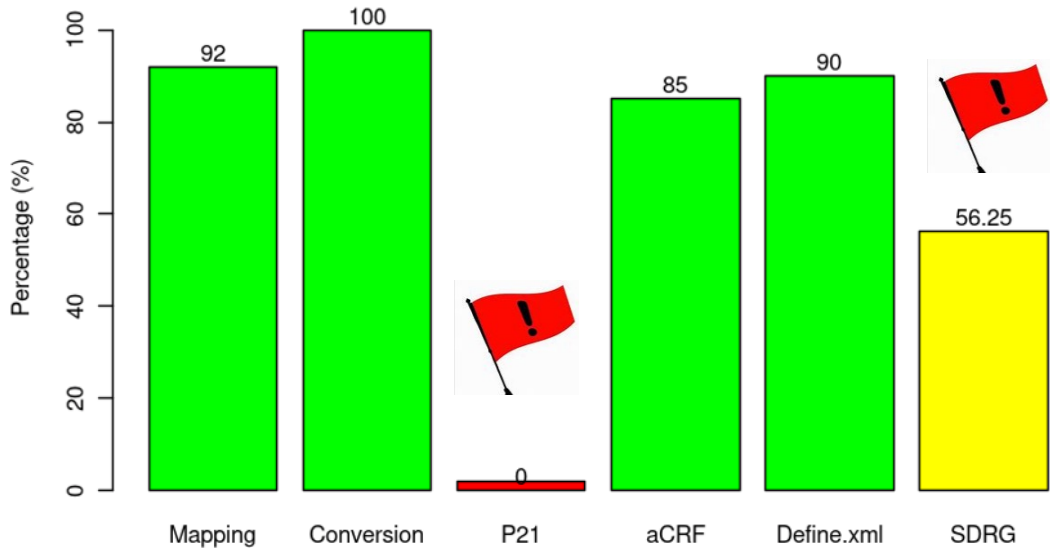
Readiness Checklist



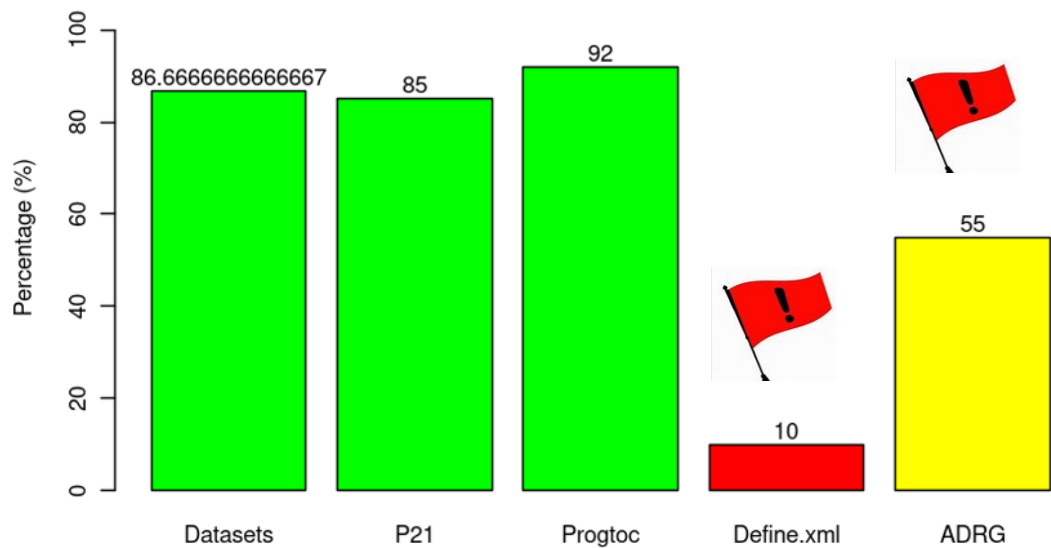
Readiness Dashboard



SDTM Plot



ADaM Plot



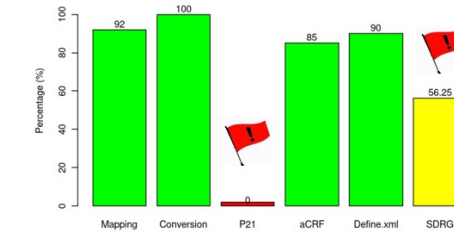
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mistry	wonderDrug	drugworks	wo12345	29 Oct 2021	NEEDS ATTENTION	MEDIUM RISK	92.00	100.00	0	85.00	90.00

Readiness Dashboard

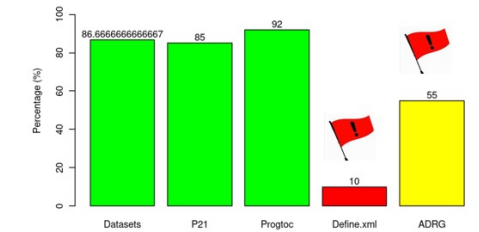


Readiness Dashboard

SDTM Plot



ADaM Plot

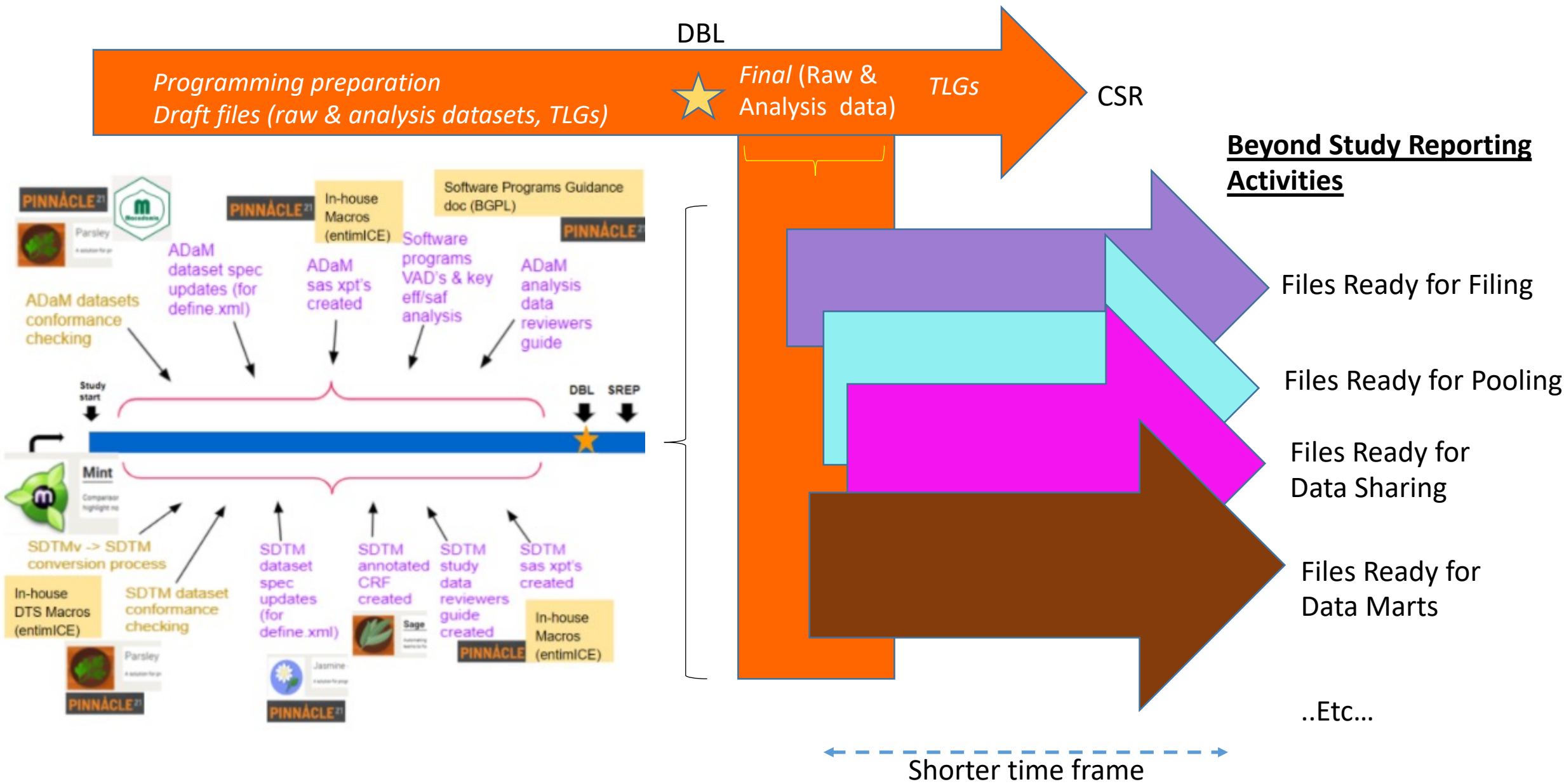


UserID	Molecule	StudyName	StudyNum	dbiDate	StudyREADINESS	StudyRISK	SDTM.Mapped	SDTM.Converted	SDTM.P21	SDTM.CRF	SDTM.Definexml
mistry	wonderDrug	drugworks	wo12345	29 Oct 2021	NEEDS ATTENTION	MEDIUM RISK	92.00	100.00	0	85.00	90.00

- Track overall progress of this work (from the readiness checklist)
- Assessment scoring (0 -100) for each component
- Assessment conducted regularly (recommended 9-6-3-1 months prior DBL)
- Incorporates DBL date to identify risk of not being ready
- Identifies activities progressing well / not so well

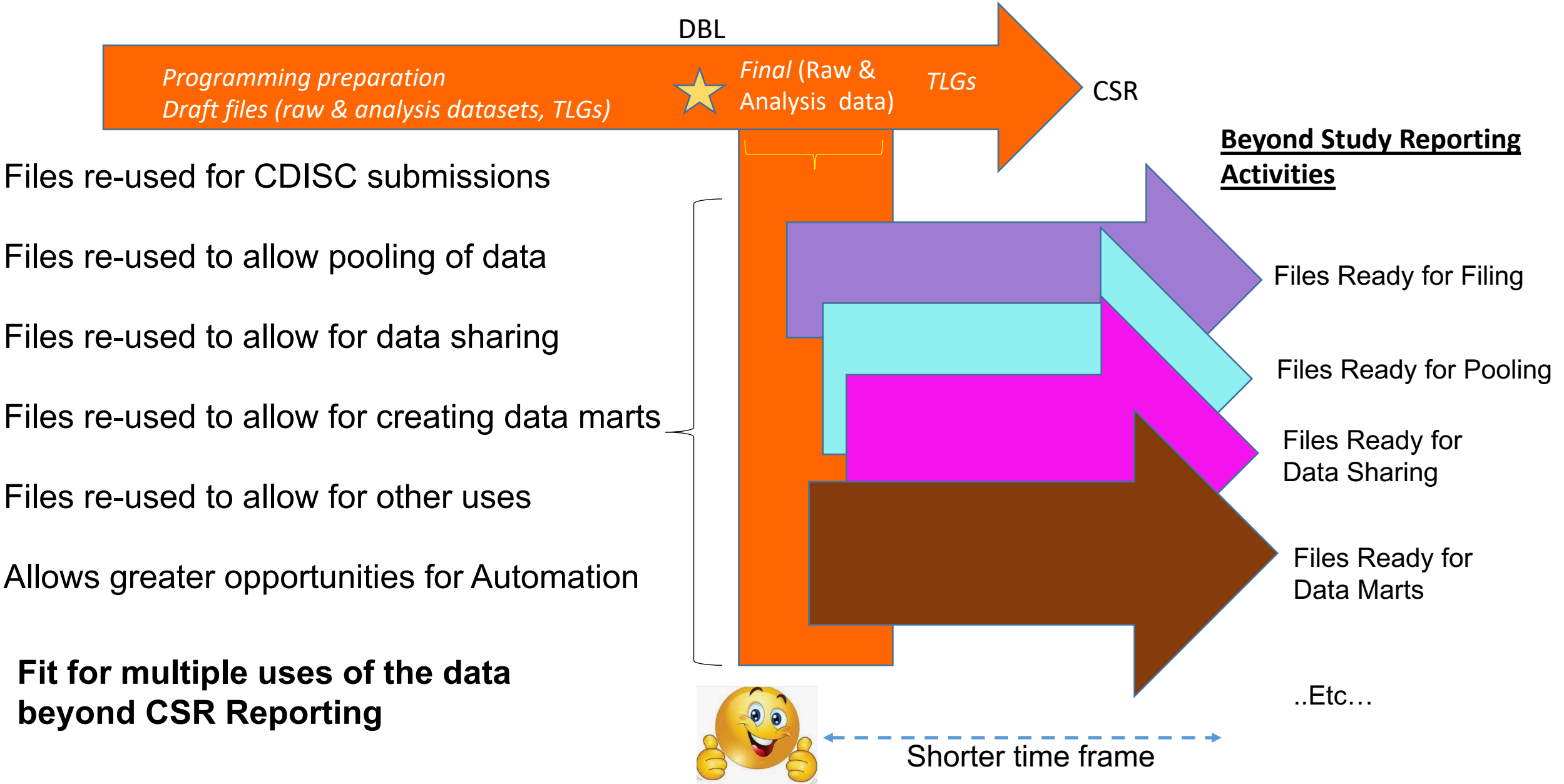
Study Level reporting

Desired State



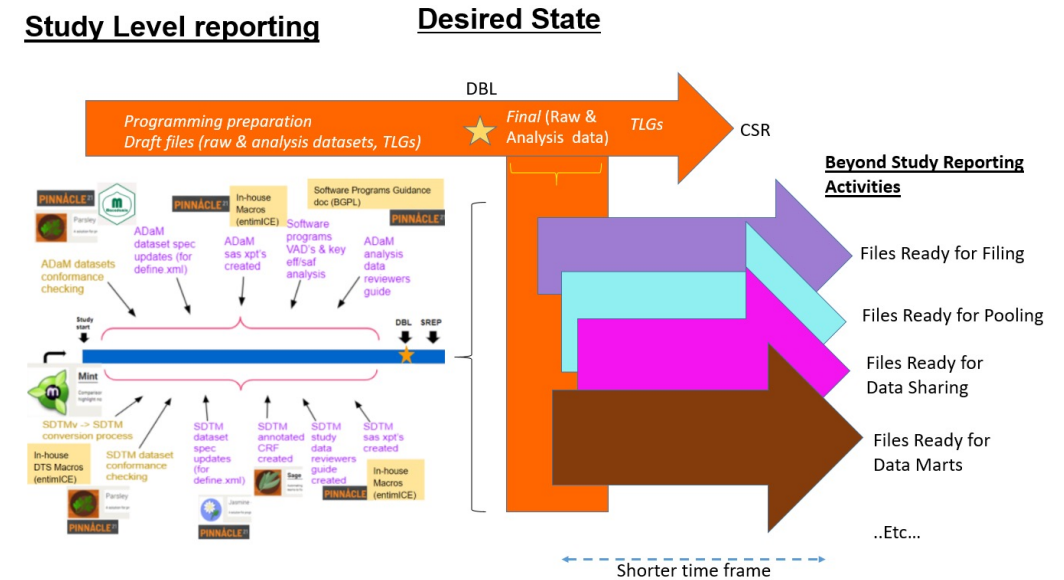
Study Level reporting

Desired State



Summary

- Think beyond CSR reporting early
- Adhere to and maintain standards early
- Implement on all studies regardless of Filing – be F.A.I.R
- Develop tools to simplify processing (efficiencies and automation)
- Longer term benefits on time, resources and re-work (FIT for multiple purposes)
- Deliver data to HA faster – benefits the patients & the business



Contact details

- For any questions feel free to contact us :
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 - Bhupendra Mistry, bhupendra.mistry@roche.com

***Doing now what patients
need next***