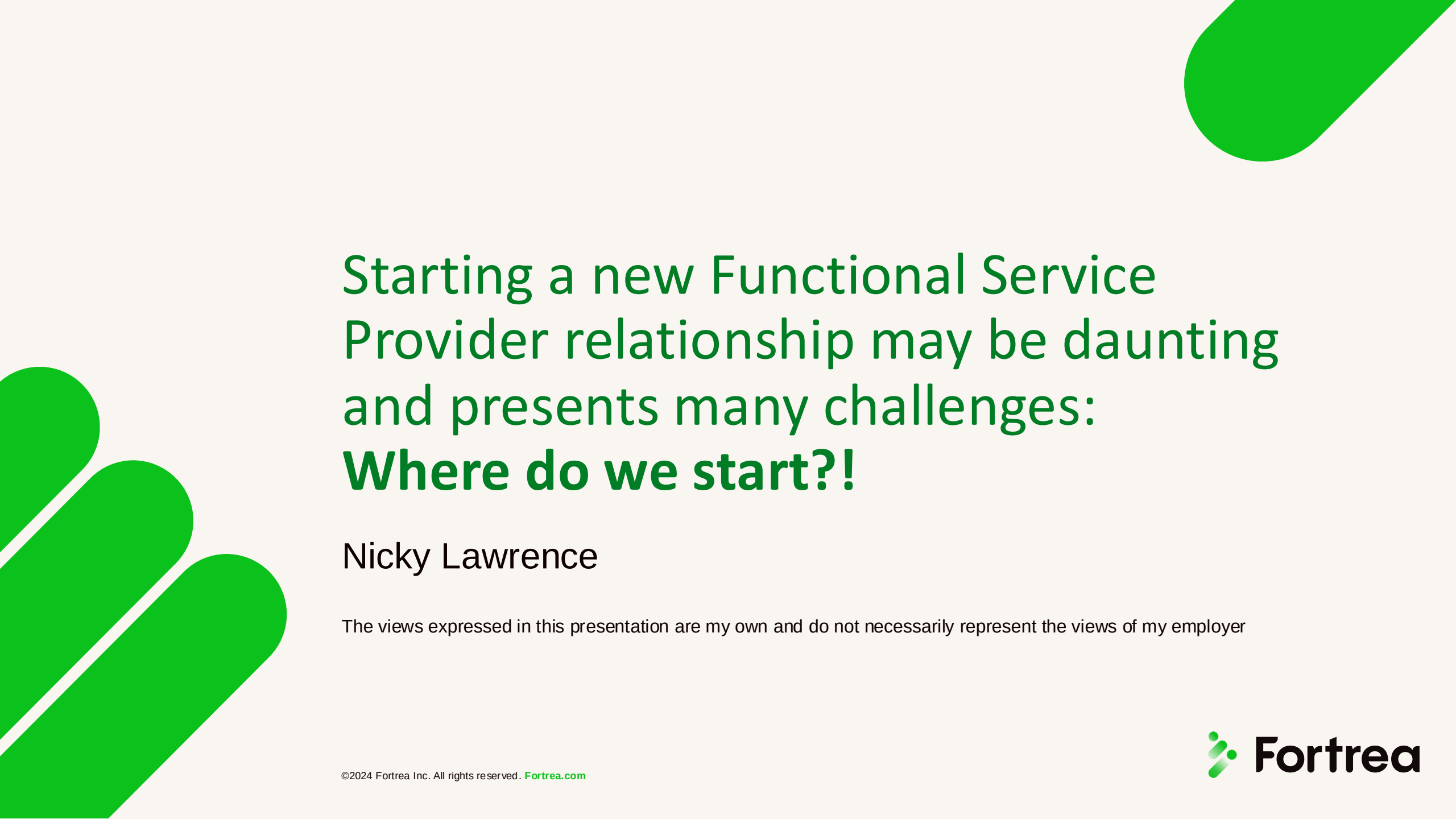




Starting a new Functional Service Provider relationship may be daunting and presents many challenges: **Where do we start?!**

Nicky Lawrence

The views expressed in this presentation are my own and do not necessarily represent the views of my employer

Award is only the beginning.....



Cultural Values



Structural Governance



Processes



Finance



Team

Kick-off Meeting (KOM) Planning



Arrange a partnership KOM

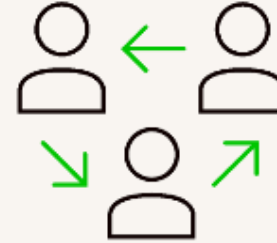
In-person or virtual

- In-person could offer opportunity to meet other personnel at that company

Logistics and attendees

Breakout groups

Agenda items



Ensure clear meeting aims

Partnership working agreements

- Budgets and MSA finalisation
- Partnership scope/scale
- Communication and culture

Agree Governance Structure

- Functional
- Operational
- Executive

Metrics and monitoring

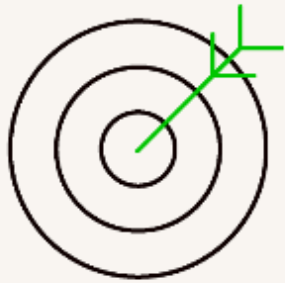
Next steps

Roles and initial set-up

- CRO project leaders
 - Who will oversee partnership direction?
 - Are multiple functions involved?
 - Seamless transition from bid -> operations
 - Stats Programming Leadership
- Staff needs
 - Internal moves?
 - Recruitment needs?
- Informing internal team
 - Awareness of new FSP
 - Staff moves or referrals
- Quality
 - Vendor evaluation
 - Quality process



Kick-off Meeting (KOM) Execution



FSP Mission

- Culture
- Governance
- Achievement aims
- Short and Long term
- Innovations



Clear Agenda

- Stick to timings
- Action list where more in-depth discussion needed
- Ensure actions are clear



Multifunctional FSP

- Meet together for overall policies
- Separate functional meetings
- Use breakouts appropriately

Sponsor or CRO Systems and Processes?

	Sponsor		CRO	
	Pro	Con	Pro	Con
Systems	Easy access for sponsor, familiarity, consistency	Access to systems, reliability of IT connections	CRO can use established processes. Can use standard costing mechanisms	Need to transfer data securely between systems
SOPs, standards, and processes	Easier integration to Sponsor extended team and sponsor control of cross study consistency	How is training of CRO team managed? How are they made aware of updates? How do process requirements fit with CRO processes?	Familiarity of working for the CRO and easier to budget	Ensuring sponsor understands all requirements.

Sponsor or CRO Process Decision

- IT considerations
 - Access to sponsor system or data transfer
- Likely mixture of SOP processes
 - Standards more important than process
 - How do you document?
 - How do you train and document training?
 - Partnership specific controlled document and/or SOP deviations?
 - Maintenance of process
- Things will change!
 - Additional task not considered
 - Changes of mind



RACI – Who does what?



RACI levels

Partnership
Functional



Look at every task and determine
involvement

Responsible
Accountable
Consulted
Informed



Interactions with other functions

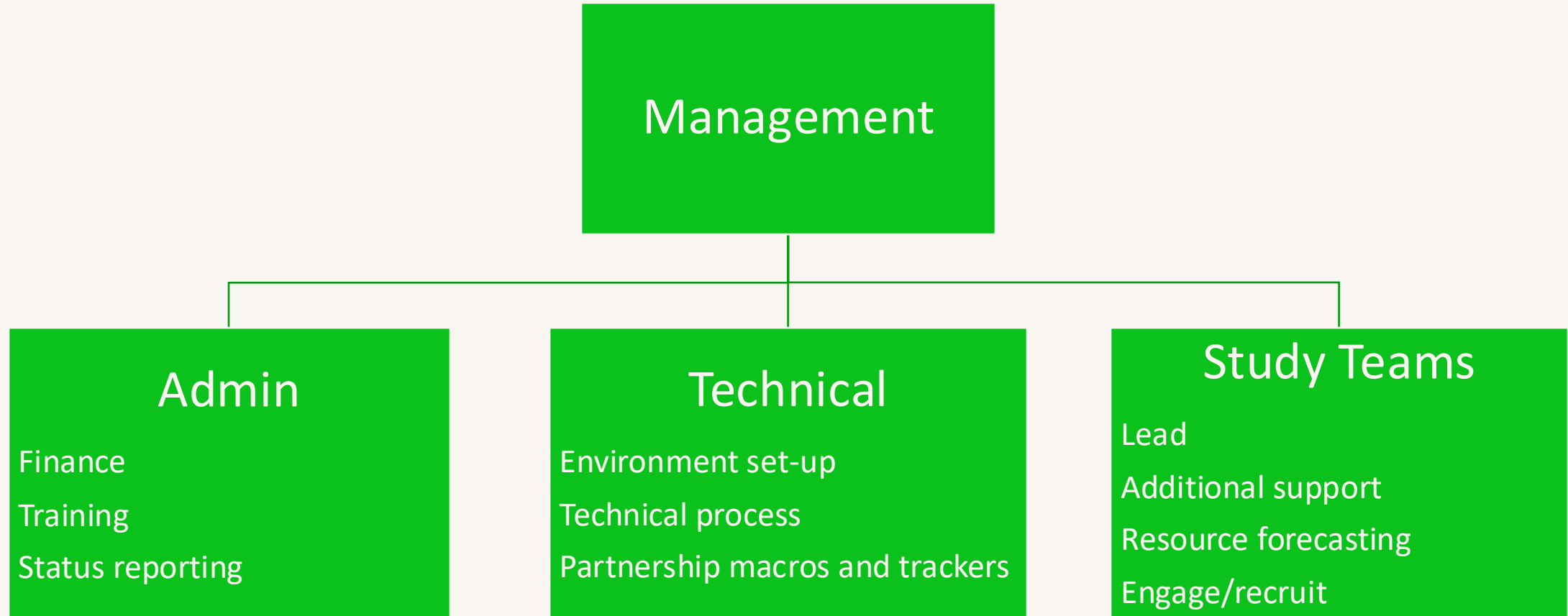
Data reviews
External data
Lock activities
PK data
TMF

RACI - Example

R=Responsible, A=Accountable, C=Consulted, I=Informed

Task Family	Task	Sponsor Stat/Prog	CRO Stat	CRO Prog	DM
SDTM	Prepare SDTM Specifications	C	C	A/R	C
	Review/Approve SDTM Specifications	A/R	I	C	
	Produce SDTM datasets	I	I	A/R	
	Produce SDTM annotated CRF	I	I	A/R	
	Review SDTM datasets and annotated CRF	A/R	C	C	
	Produce SDRG and Define.xml	C	I	A/R	

Setting up the Team



Clarify the Detail

- Provide Sponsor SOPs
- Set up Training requirement lists and documentation
- Information sharing on new processes
 - Standards
 - Training
 - SMEs and Train the trainer
- Partnership specific documentation, guidelines, forms
- TMF documentation – sharing and index
- Standard timelines
- Initial study details and forecast



Finance

MSA
Work Orders

Standard budget
worksheets and
pricing

Initial
Engagement
Agreement?

Change Order
process

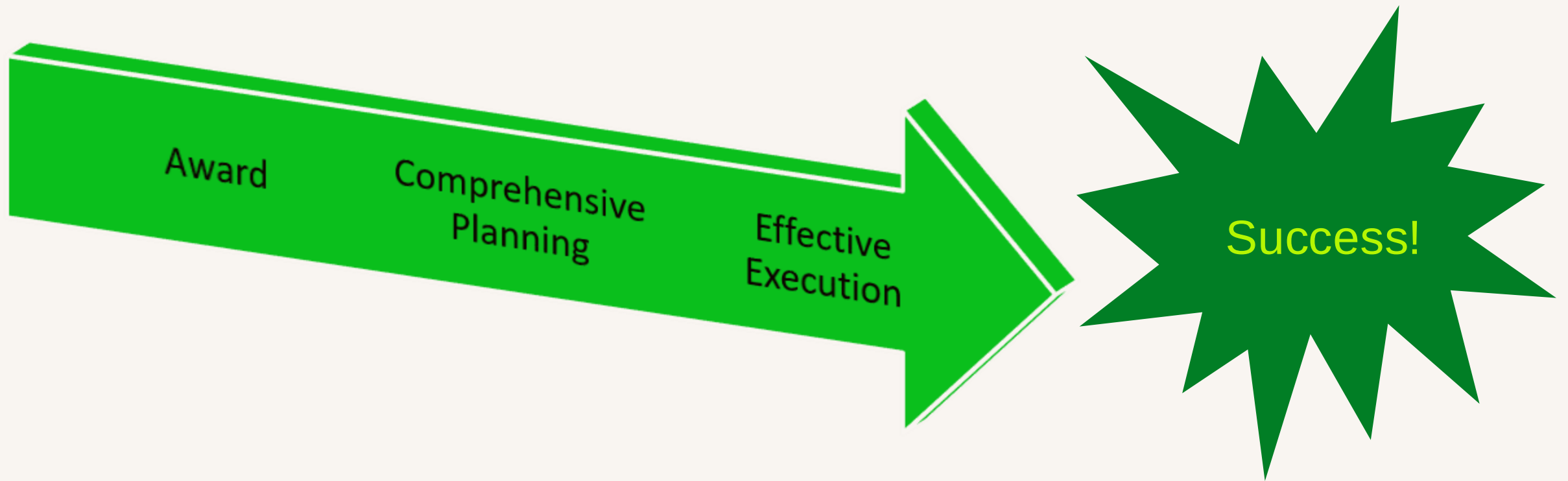
Invoice process
Milestone billing

Revenue
recognition and
forecasting tools

How do we evaluate and learn?



The Path to a Successful FSP





Questions?

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