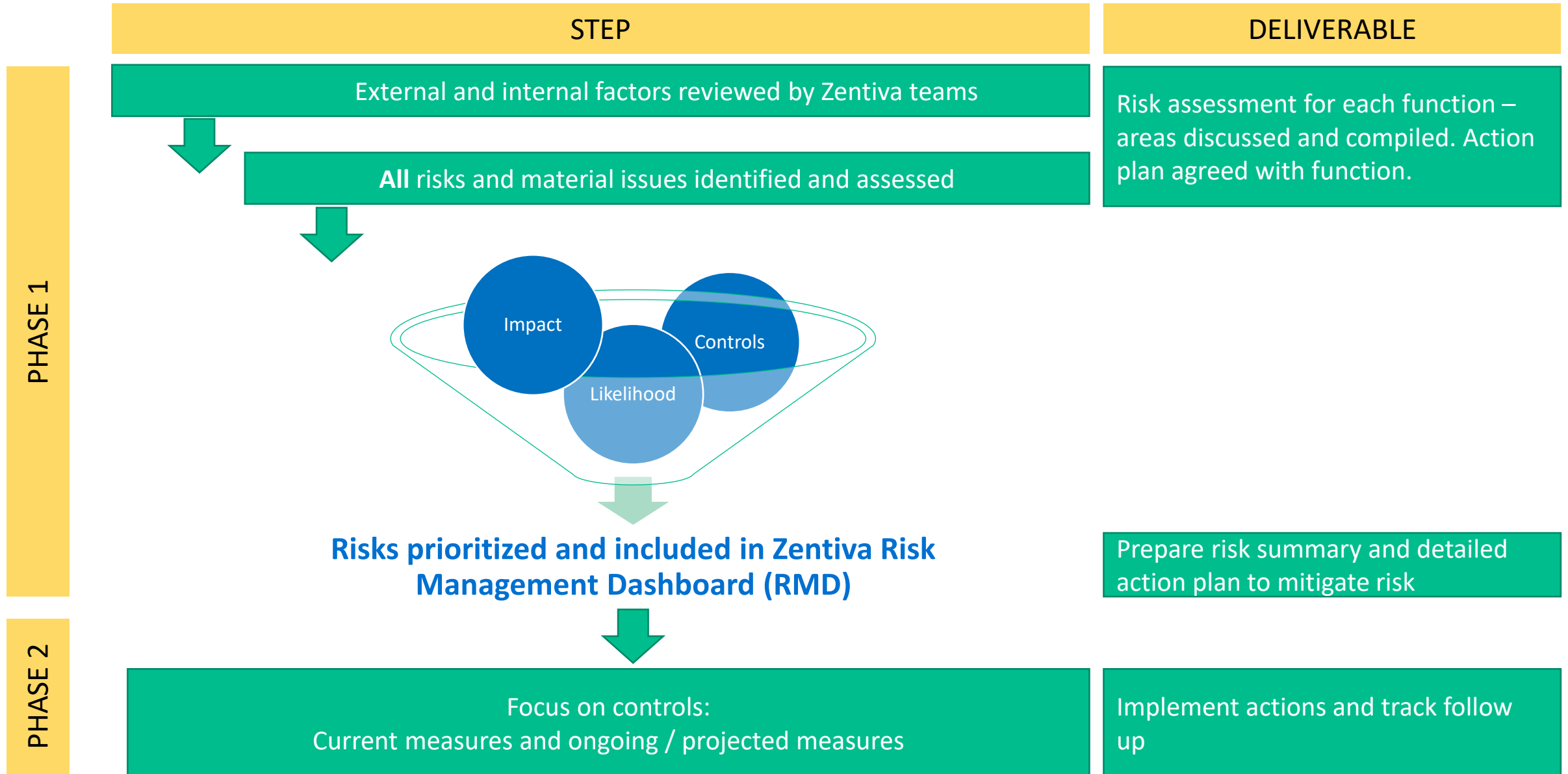


Risk assessment - key process highlights



Risk assessment tool

Pre-defined risk evaluation criteria			
Likelihood	Impact		Control effectiveness
<ul style="list-style-type: none"> Unlikely Possible Likely Certain 	Severity level		Satisfactory
	Minor	Impact, MEuro <1,5	Probably under control but require closer monitoring or improvement
	Moderate	<7,5, >1,5	Probably not controlled at the appropriate level
	Major	<15, >7,5	Not satisfactory
	Severe	>15	

Risks – pre-selected list from Zentiva risks universe was used to facilitate discussions with risk owners,

- Risk owner is responsible to confirm the key risks landscape in the area of work, so that he/ she adds/ remove risks as appropriate.

Likelihood and Impact is assessed, as if no controls in place.

- Likelihood is generally defined based on failures/ risk realization in the past and professional judgement,
- Impact: main categories - Patient, Business, Reputation; quantification drivers (for ex. potential annualized impact on cash flow, investments, EBITDA etc.) used to compare with risk evaluation criteria

Controls: identification and preliminary assessment is performed during work shops/ interviews with Risk owners.

Risk ID	PROCESS	SUB PROCESS	SPECIFIC RISKS	Risk applicable to Zentiva ?	Source of risk (what can happen externally / internally that may lead to this risk....?)	Impacts (Reputational, Business (Financial), Patient); Quantify impacts, if possible	Likelihood	Impact	Overall Assessment of control(s):	Zentiva Control(s) addressing a risk
97										
87										
tbd										
139										

Risk prioritization and Risk Management Dashboard

- Step 1** - Consolidate Risk assessment tools across all departments
- Step 2** - Risk prioritization
- Step 3** - Prioritized risks included in Risk Management Dashboard (RMD) for further monitoring
- Step 4** - Detail action plan, specify owners and timelines to manage / mitigate the risk. Track execution status

step1

Risk ID	PROCESS	SUB PROCESS	SPECIFIC RISKS	Risk applicable to Zentiva	Source of risk (what can happen externally / internally that may lead to this risk)	Impacts (Reputational, Business (Financial), Patient), Quantity impacts, if possible	Likelihood	Impact	Overall Assessment of controls	Zentiva Controls addressing a risk
97	5. Manage Medical & Quality requirements	506 Good Manufacturing & Distribution Practices	Risk of non-compliance of manufacturing and products release with Good Manufacturing Practices and Internal requirements.							
87	7. Insure & Secure	F03 Physical Building Security	Risk of inadequate security over premises or products (damage, destruction, theft,...)							
104	4. Plan to manufacture & Management	401 Equipment Facilities & Management	Risk of having aging manufacturing equipment.							
139	4. Plan to manufacture & Management	403 Equipment facilities & Management	Risk of inappropriate management of the maintenance plan and related indicators.							

Risk #	Risk	Likelihood	Impact	Current control effectiveness	Priority risk
1	[Redacted]	Possible	Severe	Satisfactory	YES
2	[Redacted]	Possible	Severe	Probably not controlled at the appropriate level	YES
3	[Redacted]	Possible	Severe	Probably not controlled at the appropriate level	YES

Step 2

Step 3

