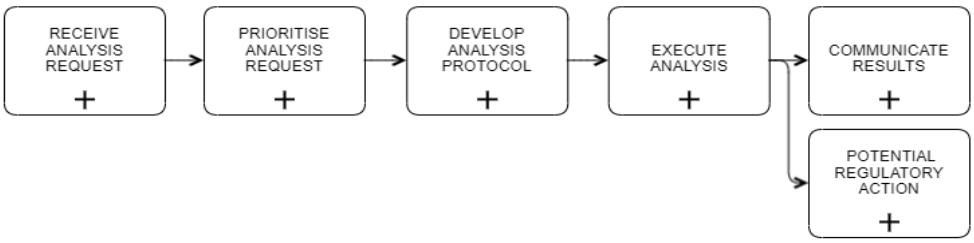
Introduction to data analysis prioritisation process

The Data Analytics Centre collaborates with both national and international partners and all analysis ideas and requests are assessed and prioritised against an agreed prioritisation model. This is done in order to provide a transparent prioritisation process based on pre-defined criteria. Based on this model potential analysis are prioritised with regards to agency obligations, impact on public health, public perception and life science impact and value. Only analysis and projects that are consideres feasible to conduct will be further investigated in the order of high, medium and low priority.

The high level process flow below illustrates how an analysis request is managed, prioritised, exuted and communicated in the Data Analytics Centre:



Analysis Prioritisation Matrix

1	Agency obligations	Weight	Yes/No	Score
1.1	Ministerial or parliamentary service	10	No	0
1.2	Market authorisation procedures	10	No	0
1.3	Post approval procedures	3	No	0
1.4	Scientific advice procedure	3	No	0
1.5	Regulatory support	1	No	0
	Sum			**0**

2	Public Health	Weight	Yes/No	Score
2.1	Increased risk of death and disability	5	No	0
2.2	> 1 of 1000 affected/drug reactions/incidents	4	No	0
2.3	>= 15,000 users/patients	4	No	0
2.4	Vulnerable population in high risk	3	No	0
2.5	Off-label use	2	No	0
2.6	Drug to treat rare disease	1	No	0
	Sum			**0**

3	Public perception	Weight	Yes/No	Score
3.1	Fright factor	4	No	0
3.2	Harmful misperceptions	4	No	0
3.3	Recent media attention (last 2 years)	3	No	0
3.4	Other public attention	2	No	0
	Sum			**0**

4	Life-science impact (Business case)	Weight	Yes/No	Score
4.1	Industry process, quality and improvements	3	No	0
4.2	Agency process, quality and improvements	3	No	0
4.3	Academia collaboration	2	No	0
4.4	Healthcare collaboration	2	No	0
	Sum			**0**

5	Feasibility	Weight	Yes/No	Score
5.1	Data availibility (access to data)	1,2	No	1
5.2	Data availibility (data has to be collected)	1	No	1
5.3	Data availibility (minimal chance of collecting data)	0,01	No	1
5.4	No. of external collaborators >= 2	0,8	No	1
5.5	DAC resources (competences)	0,01	Yes	1
	Factor			**1**

6	Score	Weight	Yes / No	Score
6.1	Score (1+2+3+4)			**0**
6.2	Score with feasibility (factor multiplied on score)	1		**0**
6.3	Final priority (High, medium, low, not feasable)			Not feasable
6.4	Override priority (High, medium, low, not feasable)			
6.5	Override reason			

Scorecard and action	
score < 1: not feasable	Analysis will not be prioritised in DAC
score >= 1 and score < 10: low	Analysis prioritised to start within 6 months
score >= 10 and score < 20: medium	Analysis prioritised to start within 3 months
score >= 20: high	Analysis prioritised to start within 1 month

#	Variable	Comment
1	**Agency obligations**	**Summarises any agency obligation that can increase the importance of an analysis, such as legal obligations, services provided to external stakeholders or requests from Ministry or parliament.**
1.1	Ministerial or parliamentary service	Ministerial support and respons parlamentary questions about pharmaceuticals and medical devices.
1.2	Market authorisation procedures	DK rapporteur or reference member state procedure.
1.3	Post approval procedures	Safety surveillance procedure. E.g. ADR signals and effect of risk minimization measures.
1.4	Scientific advice procedure	Scientific advice to industry in a pre-authorization procedure (EMA or national procedure).
1.5	Regulatory support	Improvement of in-house processes regarding quality measures and control as welll as analysis support.
2	**Public Health**	**Summarises the potential public health implications for different groups in society and the severity of impact on patients.**
2.1	Increased risk of death and disability	If increased risk of death and disability (incl. drug abuse and addiction) this will important to control for due to severe safety concerns.
2.2	> 1 of 1000 affected/drug reactions/incidents	If more than 1 out of 1000 are affected or has an adverse drug reaction or device incident it is no longer considered a rare event (according to CIOMS) and it is therefore important to adjust for due to implications on a large population.
2.3	>= 15,000 users/patients	Due to high prevalence or potential rapid uptake of a new drug it is considered important and must be accounted for.
2.4	Vulnerable population in high risk	Vulnerable population including Children, Pregnant, Elderly (individuals > 65 years) or specific patient groups and under represented populations (in RCT) are potentially at a higher risk and more susceptible to severe adverse drug reactions and must therefore be adjusted for.
2.5	Off-label use	Lack of evidence for use of the drug outside approved indication can potentially harm patients and it is therefore considered important to control for.
2.6	Drug to treat rare disease	Medical and scientific knowledge about rare diseases is lacking and therefore the data behind the drug is limited and it is considered important to adjust for.
3	**Public perception**	**Summerises the impact of public perception such as significant media attention or other public attention, the present of fright factors/scares or harmfull misperception about safety of medicine.**
3.1	Fright factor	An issue can be affected by one or more aspect of uncertainty (fright factors) such as: * Generally unavoidable by taking precautions (few clear risk factors, no specific monitoring) * Risk of cancer, teratogenicity, suicidality, or major neurogical disability. * Scientific basis is poorly understood (no known biologcal plausibility) * Experts have publicly disagreed about the existence or scale of the problem * New first in class drug
3.2	Harmful misperceptions	If harmfull misperceptions exist they can impact the public perception about a specific issue. If harmfull misperceptions are broadly communicated it can affect the patient's trust and compliance in the treatment.
3.3	Recent media attention (last 2 years)	Any recent media attention in the established media within the last 2 years regarding pharmeceuticals and medical devices.
3.4	Other public attention	Social media attention, request from public.

#	Variable	Comment
4	**Life-science impact (Business case)**	**Life science impact reflects the potential value to industry, academia, healthcare sector and agency.**
4.1	Industry process, quality and improvements	Burden relief for the pharmaceutical industry for example quality and improvements of the regulatory processes.
4.2	Agency process, quality and improvements	Burden relief for the Danish medicines agency for example quality and improvements of the regulatory processes.
4.3	Academia collaboration	Academia collaboration about quality, research and development of new methods.
4.4	Healthcare collaboration	Healthcare collaboration about quality, research and development of new methods.
5	**Feasibility**	**The feasibility depends on avaliability of data and competencies to perform the analysis and if collaboration with several stakeholders increases the overall complexity of the analysis. Factor is multiplied to overall prio-score.**
5.1	Data availibility (access to data)	Data is available in the Danish medicines agency.
5.2	Data availibility (data has to be collected)	Data has to be acquired or applied for elsewhere.
5.3	Data availibility (minimal chance of collecting data)	It as considered that data is not available or if data quality is insufficient for data analysis.
5.4	No. of external collaborators >= 2	More than two (2) external collaborators in healthcare and/or academia and/or industry.
5.5	DAC resources (competences)	Available DAC member with relevant knowledge within the subject to complete the analysis.
6	**Score**	**Total score of section 1 to 5.**
6.1	Score (1+2+3+4)	Total sum of section 1 to 4.
6.2	Score with feasibility (factor multiplied on score)	Score of 6.1 multiplied with feasibility score.
6.3	Final priority (High, medium, low, not feasable)	Final priority based on the scorecard.
6.4	Override priority (High, medium, low, not feasable)	Override priority score in special circumstances related to public health not specified in the sections above.
6.5	Override reason	Override reason in special circumstances related to public health not specified in the sections above.