

DRAFT

A vision for a national
unit for excellent
interdisciplinary research
and education within
musculoskeletal
conditions



Danish Orthopedic Academy

Danish Orthopedic Academy – DOA

The **VISION** of the Danish Orthopedic Academy (DOA) is to improve treatment and generate value for patients with musculoskeletal diseases

The **MISSION** of DOA is to establish a national elite unit for excellent interdisciplinary clinical research and education to develop patient-centered, individualized treatment of musculoskeletal diseases based on high-level clinical evidence.

The overall **STRATEGIC OBJECTIVES** are:

1. To create a strong national unit facilitating patient-centered national clinical studies of the highest scientific level
2. To develop a strong national interdisciplinary and intersectoral network by increasing collaboration across boundaries of academia, pre-clinical/clinical research and industry on national and international level
3. To educate and disseminate knowledge among musculoskeletal health care providers, patients, decision makers and the community

Background

Treatment of musculoskeletal diseases constitute a substantial part of health-care expenses. The societal cost of treatment of joint arthrosis alone is 2.5 billion DKK annually with an additional estimated loss of production of 2 billion DKK.¹ An additional 5 billion is spent on benefits and early retirement.² The most prevalent diseases in society are within the



musculoskeletal field. Low back pain is responsible for the largest loss of DALY across all disease entities in society. ¹

It is estimated that by 2050, 30% of the population will be 60 years or older.³ As musculoskeletal complaints increase with increasing age musculoskeletal diseases are expected to further burden health care costs.⁴ It is paramount to ensure that available treatments are cost-effective and provide actual value for both the patient and the society.

It has been estimated that less than 20% of orthopedic treatment is supported by high quality evidence.⁵ In other words, 80% of standard orthopedic treatment might not provide the healthcare improvements they are believed to, and some treatments could be redundant or even harmful.

There is a pressing need to investigate efficiency and efficacy of musculoskeletal treatments.⁶ A need that is heard and acted upon by the orthopedic community. Over the past decades, there has been an exponential increase in research papers investigating musculoskeletal conditions, but unfortunately the vast majority of these are of low scientific value and in high risk of bias.⁷ It is mainly small-scale studies challenged by small sample-sizes, loss to follow up and unambitious research questions.^{5,8} To significantly move musculoskeletal research and improve treatments large scale economical, methodological and logistical support is required.

The National Health Service in Great Britain has developed a national structure for the planning and execution of large-scale multicenter trials. Within the musculoskeletal field, this has resulted in a series of trials of the highest scientific level informing national and international guidelines.^{9,10,11,12,13,14} The large-scale nature of the studies has led to a pragmatic approach in term of indications and treatments. Information at the patient-level (i.e. functional level, co-morbidities, specific surgical indication, postoperative care etc.) are typically scarce. Thereby a conclusion on “the average” patient is made and a true effect of an intervention in a subgroup of the included patients treated receiving a specific treatment can be lost in the noise. The studies inform about the societal impact of a procedure, but little about the best treatment for the individual patient. As a clinician, you are left with the question; ‘How do I best treat the patient sitting in front of me?’

The Danish healthcare system is characterized by a high level of prospective systematic registration of patient specific data, which is among the most refined in the world. This unique pool of patient specific data is an unexploited resource that if used correctly can support clinical trials.^{15,16} By coupling registry data and clinical trials we will be able to account for all patients and compare with the background population. By use of large national cohorts and specific research questions and subgroup analyses we will be able to focus on specific groups of patients.

The Danish Orthopedic Academy aims to focus the clinical trial around the patient in order to inform individualized treatment selection. We want to generate clinically relevant results transferable to the individual patient.

Strategy

To improve treatment and generate value for patients with musculoskeletal diseases we need to create strong national interdisciplinary and intersectoral collaborations gathering knowledge from patients, scientific organizations, medical universities, biotech/technical universities, healthcare providers and research groups (Figure 1).

Doing so, we will create a strong national unit (DOA) facilitating patient-centered national studies of the highest scientific level. DOA will possess expertise to develop, advice, and help execute studies of the highest scientific level. The secretariat will provide services within research methodology, good clinical practice, use of national databases and registries, trials and platform studies, economy, fundraising, legal aspects, ethics and GDPR regulations.

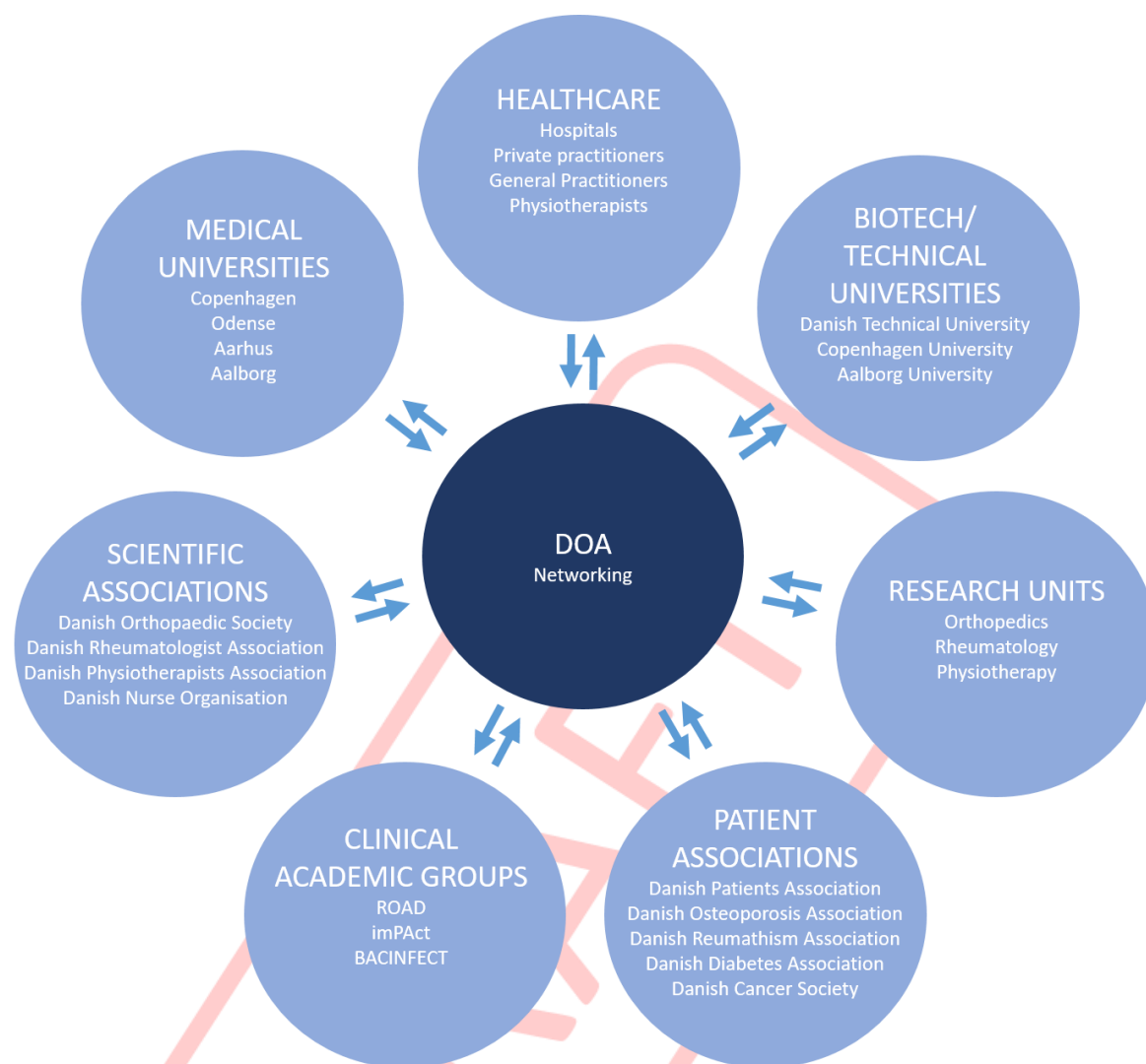


Figure 1: Important clusters in musculoskeletal research

DOA's strategy and activities are determined by the three strategic objectives (Figure 2). They are guided by the strategic focus areas and the cross cutting criteria.

DOA will facilitate interdisciplinary, population-based studies that through use of the national registries will allow for personalized medicine with high external validity.

MISSION - Establish a national elite unit for excellent interdisciplinary research and education to develop patient-centered, individualized treatment of musculoskeletal diseases based on high level evidence.

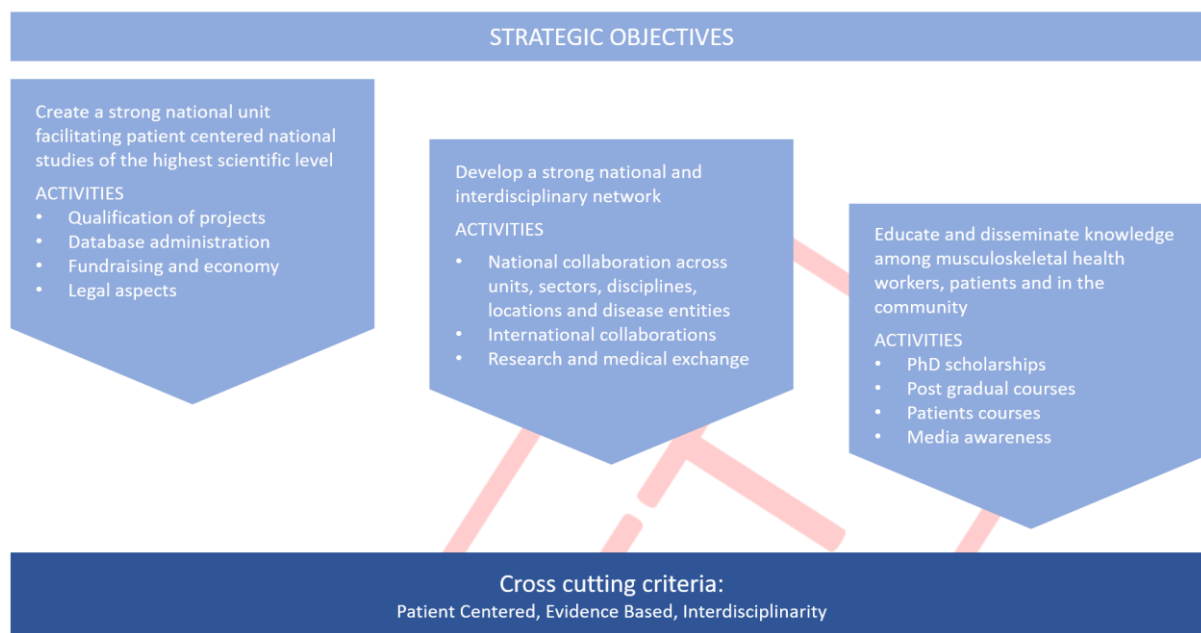


Figure 2: The strategic objectives and the cross cutting criteria work synergistically to fulfill DOA's mission

Cross cutting criteria

DOA has three cross cutting criteria implemented in all activities:

Patient centered

The patient is the center of all activities in DOA. Patients will be involved in research, education, and dissemination activities in the pursuit of evidence-based individualized musculoskeletal treatment. Patients will be involved in formation of research questions, outcome selection, methodological and logistical considerations, presentation of results, and education of both physicians and patients.

Evidence based

All activities in DOA will be evidence based with focus on the patient centered and individualized perspective. The goal is to facilitate high-level large multicenter studies supported by registry data to allow for better knowledge and evidence towards an individualized treatment.

Interdisciplinary

All activities in DOA will include contributions from multiple disciplines, multiple sectors, and multiple regions of the country. This is to facilitate network and knowledge sharing across educational, regional and national borders.

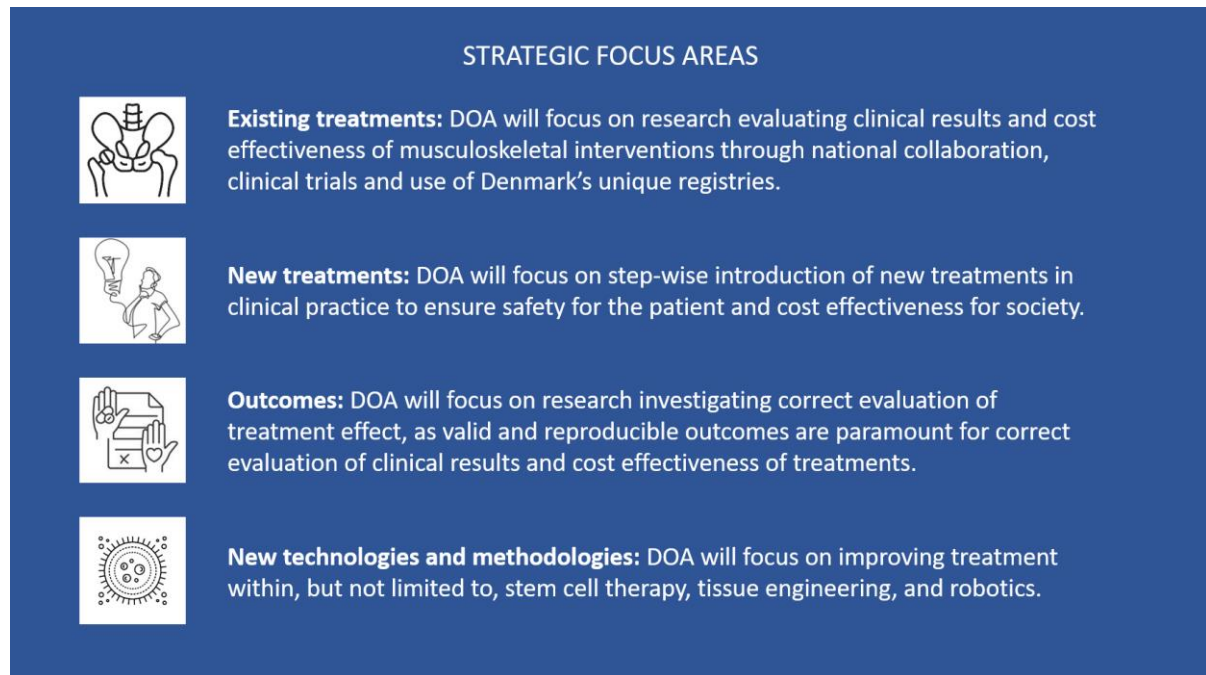


Figure 3: DOA's strategic focus areas will guide activities

Strategic Focus Areas

DOA has four strategic focus areas: Existing treatments, New treatments, Outcomes, and New technologies and methodologies (Figure 3). The strategic focus areas will guide the activities within DOA in order to reach the three strategic objectives.

Governance

The objectives of DOA's organization and governance model are to:

- Establish a Board of Directors with leading experts in musculoskeletal diseases from hospitals, academia and industry who can operate at a high strategic level
- Provide the Executive Management Director with a clear work scope, permitting efficient execution of the policies and strategies outlined by the Board of Directors

- Establish a transparent organizational structure with feedback and feedforward from the organization

Accordingly, we propose the following governance structure consisting of a Board of Directors, an Executive Management Team, a Research Facilitation Unit, and a Grant Committee (Figure 4).

The governance structure is implemented in phases according to the growth of the organization. First, the Research Facilitation Unit is established (Phase 1). With the growth of the unit, the Executive Management Team and the Board of Directors are established (phase 2). When major funds are acquired, the Grant Committee is established to evaluate and manage distribution of grants (phase 3).

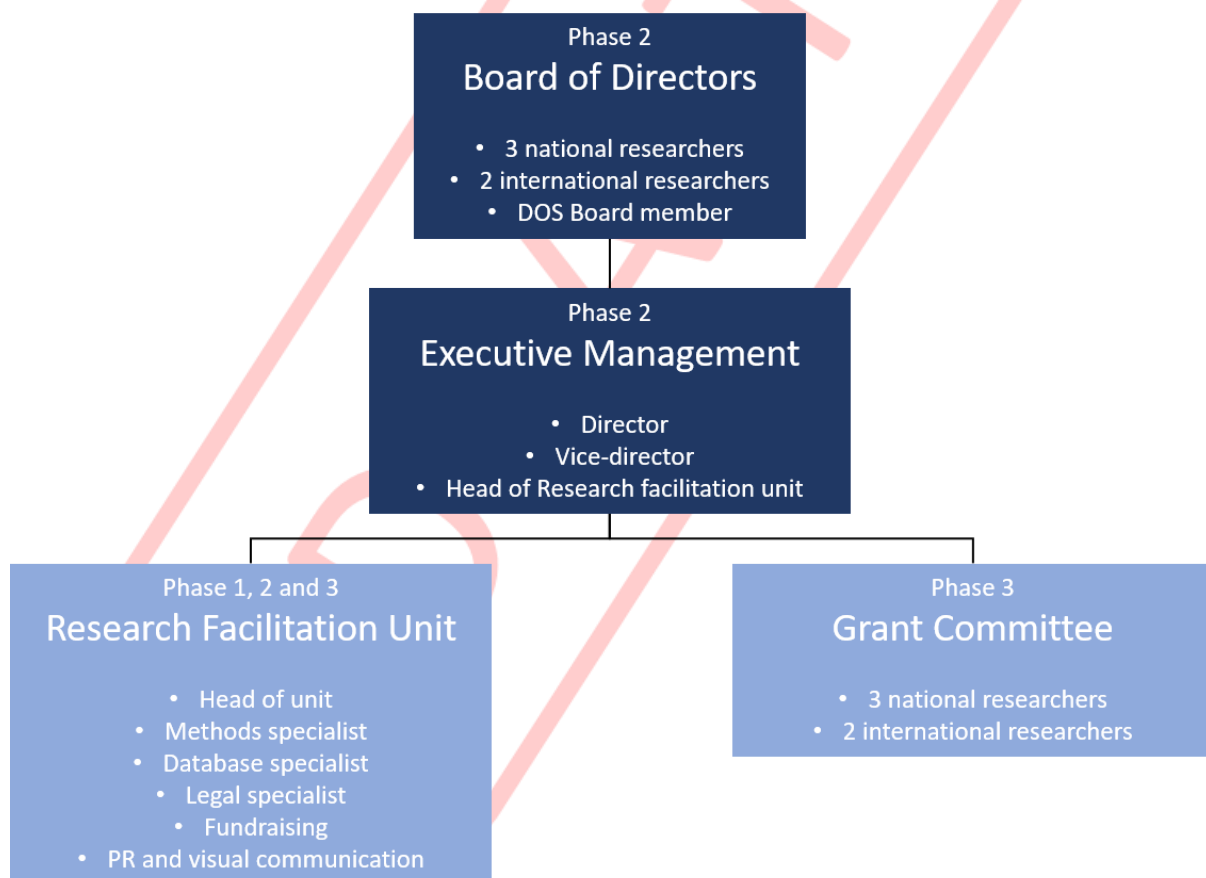


Figure 4: Diagram of the governance structure and the phases-wise implementation

Time plan

DOA is established in three phases: an initiation phase, a development phase, and a full-scale phase (Figure 5).

The initiation phase is characterized by information about DOA and consolidation of support from the orthopedic community. The research facilitation unit is initiated in a low budget version and the first two national multicenter studies are initiated. Major funding parties are approached.

The development phase is characterized by development of the research facilitation unit and initiation of further seven national multicenter studies. The executive management and the board of directors are established. An application for major funds is drafted and submitted.

The DOA full scale phase is entered when the major funds are granted. The grant committee is established and PhD grants are awarded.

		Initiation
Phase 1	2023	Consolidation of support from the orthopedic community First national DOA meeting Establishment of the Research Facilitation Unit Research assistant (50%) Director (10-20%) Research Committee (3-5 persons) Graphical design, web page (external) Funding through DOS, orthopedic departments and minor funds
	2024	Minimum 2 multicenter trials initiated Funding for onsite project workers in trials Funding through DOS, orthopedic departments and minor funds Major funding parties approached

Phase 2	Development	
	2025	Minimum 3 (new) multicenter trials initiated Method specialist hired Funding achieved for research assistant (100%) Funding through DOS, orthopedic departments and minor funds. Draft of application to major funding parties
	2026	Minimum 4 (new) multicenter trials initiated Funding achieved for new research assistant and method specialist Application for major funding parties submitted Approach other societies if necessary Funding through DOS, orthopedic departments and minor fund
Phase 3	DOA full scale	
	2027	Grant Committee Established Funding through major funding party

Figure 5: Time plan for upstart of the Danish Orthopedic Academy

Budget

The upstart of DOA is planned over four years with increasing activities and thereof increasing budget. In year five DOA is expected to receive major funding in order to scale the activities and start distributing grants.

Budget - Upstart of the Danish Orthopedic Academy						
Expenses	Unit price	Total	Dived per year			
			2023	2024	2025	2026
Office		700.000	100.000	200.000	200.000	200.000
National DOA meeting		200.000	50.000	50.000	50.000	50.000
DOA research assistent	225	1.947.996	216.432	432.891	432.891	865.782
DOA on site project worker	250	5.130.560		641.320	1.603.300	2.885.940
Graphical design / web	250	86.833	40.083	9.250	18.750	18.750
Statistician	300	432.891	48.099	96.198	144.297	144.297
Methodologist	300		48.099	48.099	96.198	96.198
Total		8.498.280	502.713	1.477.758	2.545.436	4.260.967
Financing						
DOS		500.000	250.000	250.000	0	0
Orthopedic departments		1.750.000	250.000	500.000	500.000	500.000
Housing department		1.750.000	250.000	500.000	500.000	500.000
External funding		5.050.000	0	250.000	1.500.000	3.300.000
Total		9.050.000	750.000	1.500.000	2.500.000	4.300.000

Notes

Office	Includes upstart of office, meeting facilities, board and travel at meetings
National DOA meeting	National meeting for researchers within musculoskeletal research
DOA research assistent	50% first year, 100% next two years, two research assistent in 2026
DOA on site project worker	App. 1 months work per trial at 8 centres
Graphical design / web	App. 1 months work for initiating web page and graphical design
Statistician	App. 1 months work in year 1, 2 months in year 2 and 3 months in year 3+4
Methodologist	1 months work in year 1 and 2, 2 months in year 3 and 4
DOS	Application will be made to the Danish Orthopedic Society
Orthopedic departments	25 orthopedic departments in DK providing in average 20.000DKK each
Housing department	The advantage of housing DOA will be reimbursed through a larger donation
External funding	Fundraising will be performed for the individual trials and for DOA

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