



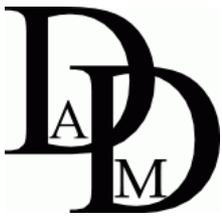
Agenda for Medlemsmøde & Generalforsamling 27. Januar 2016

15.00- 15.30: Agenda for Generalforsamlingen (hos Larix) :

1. Valg af dirigent
2. Formandens beretning
3. Præsentation og godkendelse af regnskab 2015
4. Præsentation og godkendelse af budget 2016 og aktiviteter
5. Valg af bestyrelse
6. Indkomne forslag
7. INCDMA statute review – short presentation
8. evt.: ændring af vedtægter

15.30-15.45: Pause

15.45-16.45: GCP-inspektioner – datalister til inspektionsforberedelse samt udvalgte afvigelser vedrørende DM, elektroniske systemer m.m



Formanden's Beretning 2015

Bestyrelsens Opgaver:

- Bestyrelsesmøder
- Planlægning og forberedelse af medlemsmøder
- Planlægning og forberedelse af kurser
- Netværk – deltaget i INCDMA telefon konference møder (International Network for CDM Associations)

Kurser /Events i 2015:

- **Sommer Event i Juni (SAS Institute)**
 - Validation of Excel Spread sheets at Barvarian Nordic
 - QA point of view
 - Demo of technical implementation of security module
 - Presentation of SAS JMP
 - Guided tour at the Opera
 - Dinner in Nyhavn

Medlemsmøder i 2015:

• **Generalforsamling 2015 hos Novo**

• **General forsamling**

• **Foredrag med Birger Brodin og Johan Olsen om 'serendipity'** (er det at finde uden at søge, men derefter også at erkende værdien i det, man har fundet, sådan at det ses i et helt nyt lys. To af det [20. århundredes](#) store opdagelser, [røntgenstrålerne](#) og [penicillinet](#), blev gjort ved opmærksomhed over for tilfældige og uventede resultater under laboratorieforsøg.)

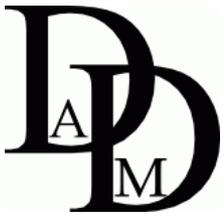


Formanden's Beretning 2015

Planlagte Aktiviteter I 2016:

- GCP kursus med fokus på data management
- 1-2 medlemsmøder
- Er der stemning for endnu et CDISC kursus evt. advanced?

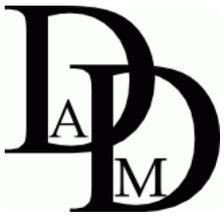
Yderligere Input til aktiviteter I 2016 modtages gerne!



Formanden's Beretning 2015

Dato for Bestyrelsesmøder og medlemsmøder samt øvrige aktiviteter i 2016:

Disse aktiviteter vil først blive planlagt efter general forsamlingen, når den nye bestyrelse er blevet konstitueret.



Formanden's Beretning 2015

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INCDMA statute – Background

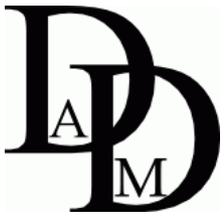
Background:

The UK-based Association for Clinical Data Management (ACDM) and the French Data Management Biomedical (DMB) initiated international contacts among Clinical Data management groups in the year 2000.

Representatives of associations in Germany, the Nordic region, Australia and the US were identified and an informal Network of e-mail contacts and quarterly teleconferences were initiated. These representatives wished to continue the information exchange and discussions of relevance to our member associations but also felt it important to establish a truly international body, recognized by the "profession".

The International Network of Clinical Data Management Associations (INCDMA) has continued to hold regular Teleconferences and several additional countries has joined.





INCDMA statute – Background cont..

Background:

Examples of themes covered by INCDMA:

- EDC, eClinical, eCOA, RBM, eSource
- Quality Control
- Data Standards, CDISC
- Laboratory Data / Medical Coding
- Good Clinical Data Management Practices
- Professional Development



INCDMA statute – Designation

Designation:

The **International Network of Clinical Data Management Associations (INCDMA)** is a permanent working group, comprised of members of the established Clinical Research Data Management professional associations and focus Groups.

The INCDMA is an independent discussion and thinking group with the aim to facilitate collaboration among CDM professional organizations around the world.

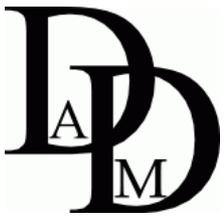


INCDMA statute – Constitutive Act

Constitutive Act:

In the beginning of 2015 the INCDMA decided to further formalize its existence. In the interest of transparency, the present document was devised. *It was also decided that a small coordinating committee would be tasked with representing the Network and its member associations to other industry stakeholders and the authorities.*

The Network has no formal headquarters. Contact and administrative support are provided as a courtesy of the constitutive data management professional associations.



INCDMA statute review – Budget and Assets

Budget and Assets:

The INCDMA has no formal membership fees - nor accepts any individual or corporate capital donations.

The usual practice is that a small donation proportionate to the number of members represented by each constitutive professional association is forwarded to a bank account at the beginning of each calendar year.

There is no salary or other compensation to be expected for any INCDMA participant or sponsor.

There is no asset or intellectual property of INCDMA other than our peer-reviewed documents, articles, publications and presentations, the written, visual or recorded content of training sessions and webinars, posters and the INCDMA logo.

Based on the above there is no passive or liabilities allowed for the INCDMA - neither the members nor the coordinating committee can engage in contracting loans or any other form of obligation on behalf of the INCDMA, with any 3rd party within or outside the Network.



INCDMA statute – Membership and code of conduct

Membership and code of conduct:

The INCDMA is a network of named individuals. There are no group or corporate memberships and memberships are not transferable at the discretion of the members themselves.

Members of the Network are appointed by their respective professional association - preferably from the boards or steering committees or board of trustees of those associations, but that is not a formal requirement.

The INCDMA (and each professional association for its registered members and affiliates), reserve the right to request the exclusion of any individual who by their actions or omissions shows non-compliance with the principles set forth in The Statute.

Members are expected to candidly and fearlessly share their opinions within the group in writing or orally.

The INCDMA does not harbor any unlawful activity and will fully disclose potentially incriminating information at the request of legal authorities - but will not respond to solicitation by any moral, religious or state authority which disregards international agreements for the safety and protection of patient and human trial subjects' rights, impedes scientific progress or otherwise deviates from established and mutually accepted principles set forward by the UN and WHO.

The INCDMA will consistently comply with the strictest legal standard in effect when it comes to data privacy, data security and anti-trust legislations.



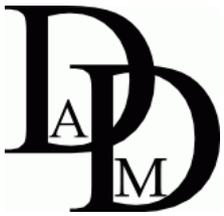
INCDMA statute – Membership and code of conduct cont..

Membership and code of conduct:

Decisions within the Working Group are taken by means of open consultation and non-secret voting.

At the request of any member a secret vote can be organized - but then a secure and complimentary electronic voting system will need to be temporarily made available to all members of the working group.

Decisions, communications, opinions, recommendations, review of peer publications and candidate standards (INCDMA “Positions”) and any other action **“in name of”** the INCDMA are unanimously approved by all working group Members.



INCDMA statute – Coordinating Committee

Coordinating Committee: (examples of it's objectives)

- facilitate and provide administrative support to the activities of the Network (i.e. plan and organize meetings, teleconferences, webinars and offline communications)
- represent the Network to the constitutive member organizations and to any third party
- review and pre-approve modifications of the Network's statute and essential documentation and prepare them for presentation to the full working group for final approval
- respond to public enquiries

Coordinating Committee: Consists of the following positions:

- The Chair
- The Secretary
- The Trustees



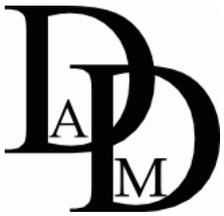
INCDMA statute – Duration and Dissolution

Duration and Dissolution

Modifications to the statute, to the designations of the INCDMA-CC as well as a formal decision to dissolve the INCDMA will have to be taken unanimously by all constitutive and working group members.

The INCDMA will be dissolved automatically if there are less than 3 accredited CDM professional associations - and the Network fails to secure sufficient representation in the major ICH-GCP geographical areas (NA, EU and Japan). In the event that the Network is dissolved, after making and receiving outstanding payments, the Coordinating Committee will pass any remaining funds to a nominated global charitable organization or not for profit association.

The INCDMA reserves the right to identify (unanimously only) an existing professional association which will decide to continue the INCDMA projects on behalf of the international DM and Programming community - but only under the condition that the principles, objectives and operating mode detailed in this document are also adhered to. It is important to be able to ensure complimentary or free access to such a future Network and its deliverables even for data professionals who due to location or material limitations cannot afford a paid subscription to an existing association.



INCDMA statute – Establishment as a non-profit association

Establishment as a non-profit association

The INCDMA reserves the right to transition to a non-for-profit association if a majority of the members requests it and the conditions are met for a viable, permanent, established presence of a bureau and registered address in a region within the GCP space.



INCDMA statute – Mission and Values

Mission and Values

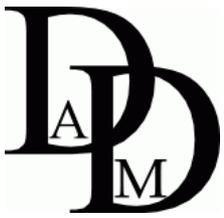
- Further the globalization, development and professional conduct of Clinical Research Data Management by Promoting collaboration among Data Management associations and groups around the world and by providing an international forum for discussion and feedback on current topics of relevance to the discipline.
- Develop an inventory of documentation available amongst its members, which will include both procedural (constitutions, bylaws, policies, etc.) and operational (training materials, laboratory data guides, GCDMP, coding references, etc.) documentation.
- Collaborate with industry fora, such as DIA CDM and eClinical SIACs representatives to co-ordinate reciprocal arrangements for promotion at conferences and involvement of INCDMA in program committees for DIA CDM and eClinical related workshops.
- Compile a list of documents for review. Distribute documents to experts for peer review. Provide global input to relevant draft regulatory documents and identify documents for further review.
- Further its knowledge of and influence in EDC, eSource, RBM and eCOA topics by liaising with relevant professional associations and discussion groups, researching and reviewing relevant upcoming guidelines and regulatory references



INCDMA statute – Mission and Values cont...

Mission and Values

- Collaborate with different organizations to produce training webinars or tutorials or courses offered to all the countries participating in INCDMA.
- Analyse the future of the DM role. Define and identify additional and changing skill sets, requirements and training needs.



INCDMA statute

Individual statement of conformance and adherence to the principles and objectives of the INCDMA:

6.4. Template Individual Statement of conformance and adherence to the principles and objectives of the INCDMA

<p>I hereby certify that I adhere to the mission and principles of the INCDMA. I engage to promote the Network in good faith and in accordance to the established principles set forth by good clinical practice and the code of conduct of my professional association and the context defined by applicable international and national regulatory requirements.</p>	
<p>(Print Name and affiliation, date)</p>	<p>(Signature)</p>