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(2) JRC Directorate I – Competences. I.3 Text and Data Mining.

RESULTS

Aim

- ## Objectives

- ## APPROACH

| Country | Regulatory authority | Websites (only english version) | Products regulated |
|--------------------------|--|---|--|
| Australia | Therapeutic Goods Administration (TGA) | www.tga.gov.au | Medicines Medical devices Cosmetics; Biologicals; Blood and tissues Drugs |
| Brazil | Brazilian Health Surveillance Agency (Anvisa) | portal.anvisa.gov.br | Drugs Food; Cosmetics; Blood, tissues and organs Drugs |
| Canada | Health Canada, Health Products and Food Branch (HC) | www.hc-sc.gc.ca | Medical devices Pharmaceuticals |
| Japan | Ministry of Health, Labour and Welfare | www.mhlw.go.jp | Food Drugs |
| | Pharmaceuticals and Medical Devices Agency (PMDA) | www.pmda.go.jp | Medical devices Drugs |
| Republic of Korea | Ministry of Food and Drug Safety (MFDS) | www.mfds.go.kr | Medical devices Food; Agro-Livestock and Fisheries; Biologics; Cosmetics Medicines |
| Russian Federation | Roszdraznadvzor (Federal Service for Control over Healthcare and Social Development) | www.roszdravnadzor.ru | Medical devices Western medicine |
| Singapore | Health Sciences Authority (HSA) | www.hsa.gov.sg | Medical devices Complementary Health Products; Cosmetics; Tobacco control |
| Switzerland | Swiss Institute of Therapeutic Products (Swissmedic) | www.swissmedic.ch | Medicinal products Medical devices Drugs |
| United States of America | U.S. Food and Drug Administration (FDA) | www.fda.gov | Medical devices Food; Radiation-emitting products; Vaccines, blood and biologics; Animal and Veterinary; Cosmetics; Tobacco Products Human medicines |
| European Union | The European Medicines Agency (EMA) | www.ema.europa.eu | Veterinary medicines Herbal medicines for human use |
| | Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG Growth) | http://ec.europa.eu/growth/sectors/medical-devices/ | Medical devices |
| Taiwan | Taiwan Food and Drugs Administration (TFDA) | www.fda.gov.tw | Human drugs Medical devices |
| | | | Food |

Web crawling of regulatory authorities websites

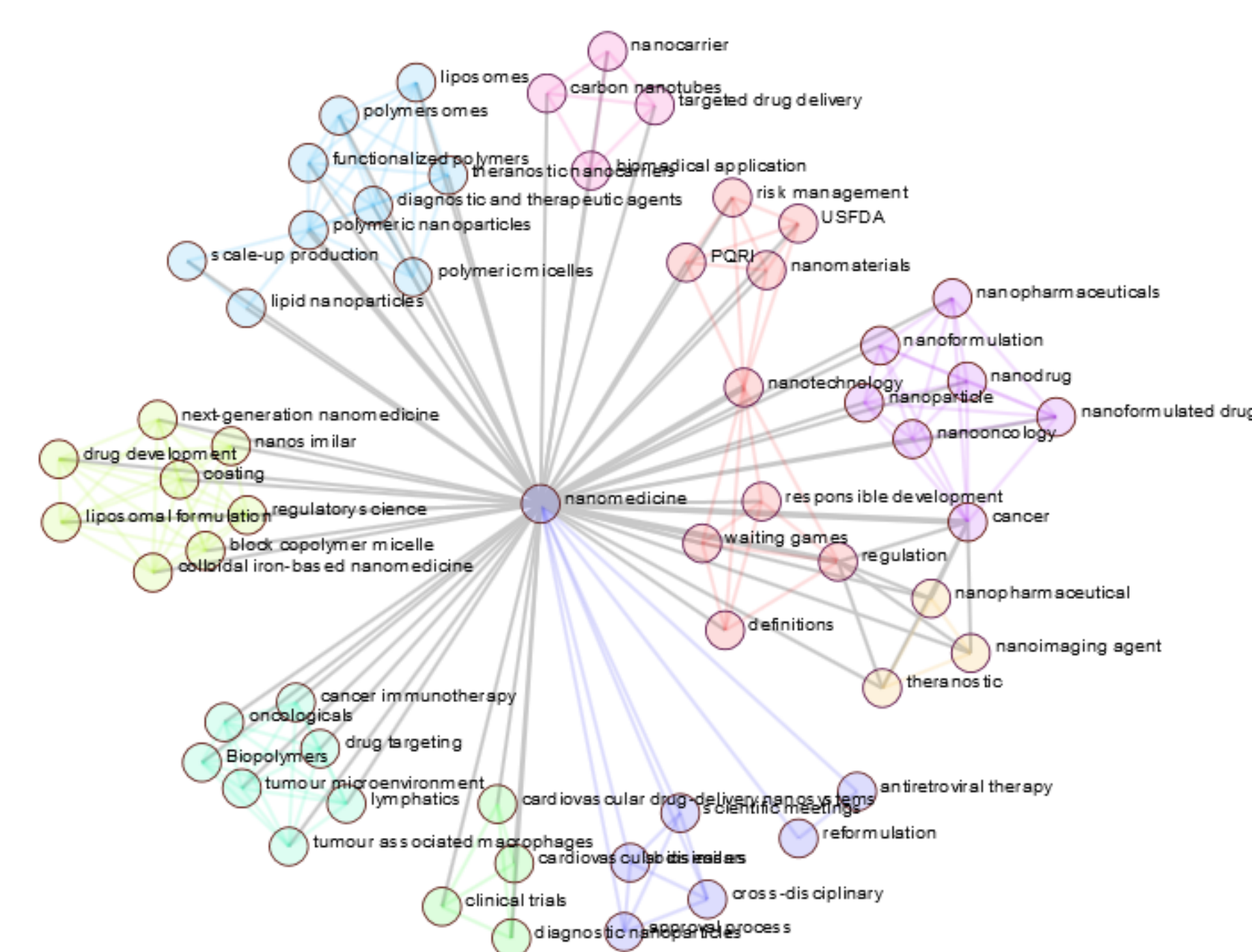
- Text-mining and term extraction



Data curation and consolidation

Term frequency and selection

Identification of terms associated with the nanotechnology application in health



- Bibliometric analysis allowed an automatic retrieval of most frequent and relevant keywords and the relations between them (keyword co-occurrence information: two or more keywords occur together in the same publication, patent or EU project description)
- The graph visualises the complexity of terms used in the field of nanomedicine and reflects communication challenges faced by stakeholders involved in translational nanomedicine
- Nodes and edges represent terms and their co-occurrence frequency, respectively. Colours are highlighting clusters, not interpreted here.

Figure 2 Regional variability terminology in number of terms. This chart shows the number of terms identified in each regulatory authorities' website matching the training set (385 terms).

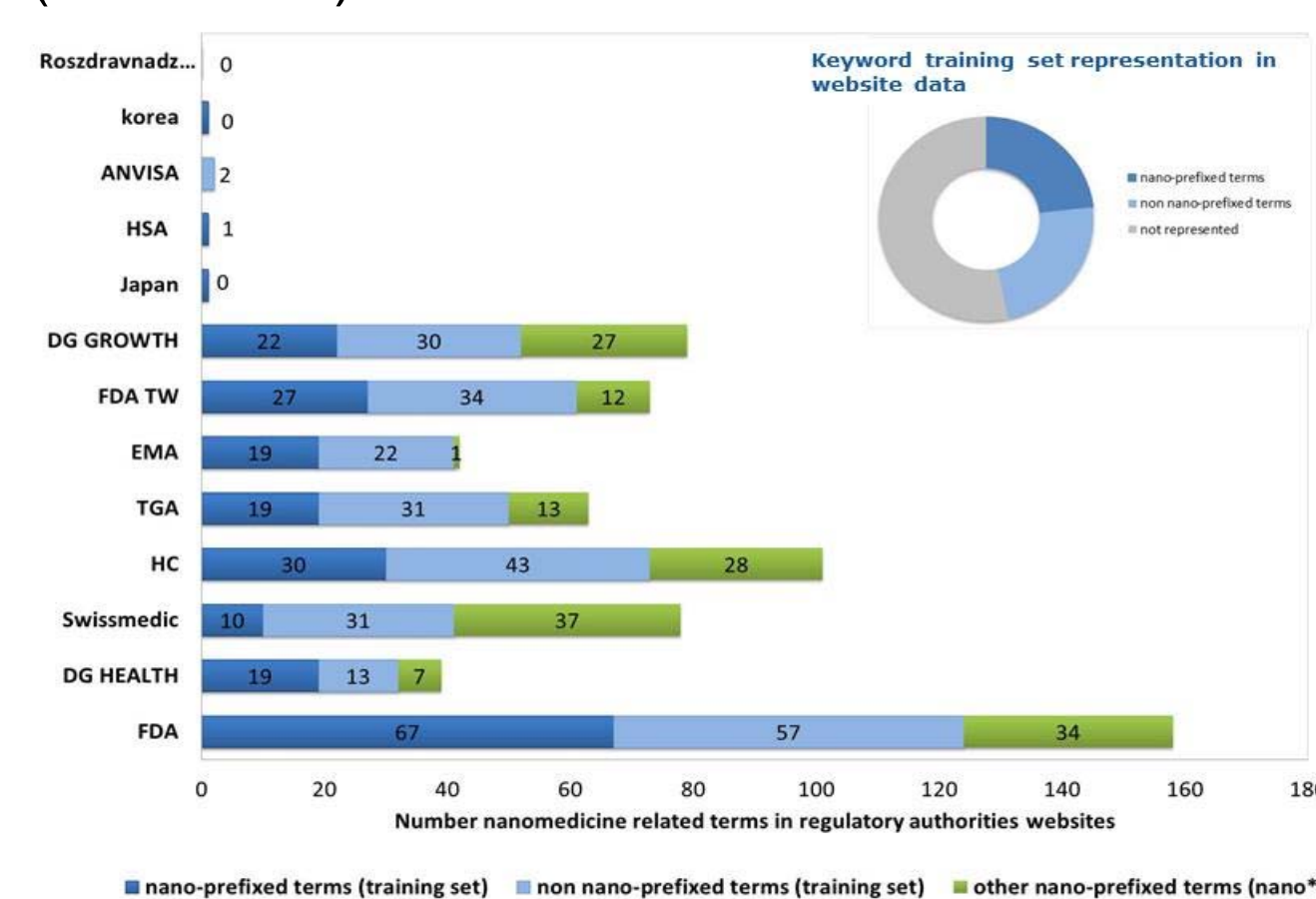
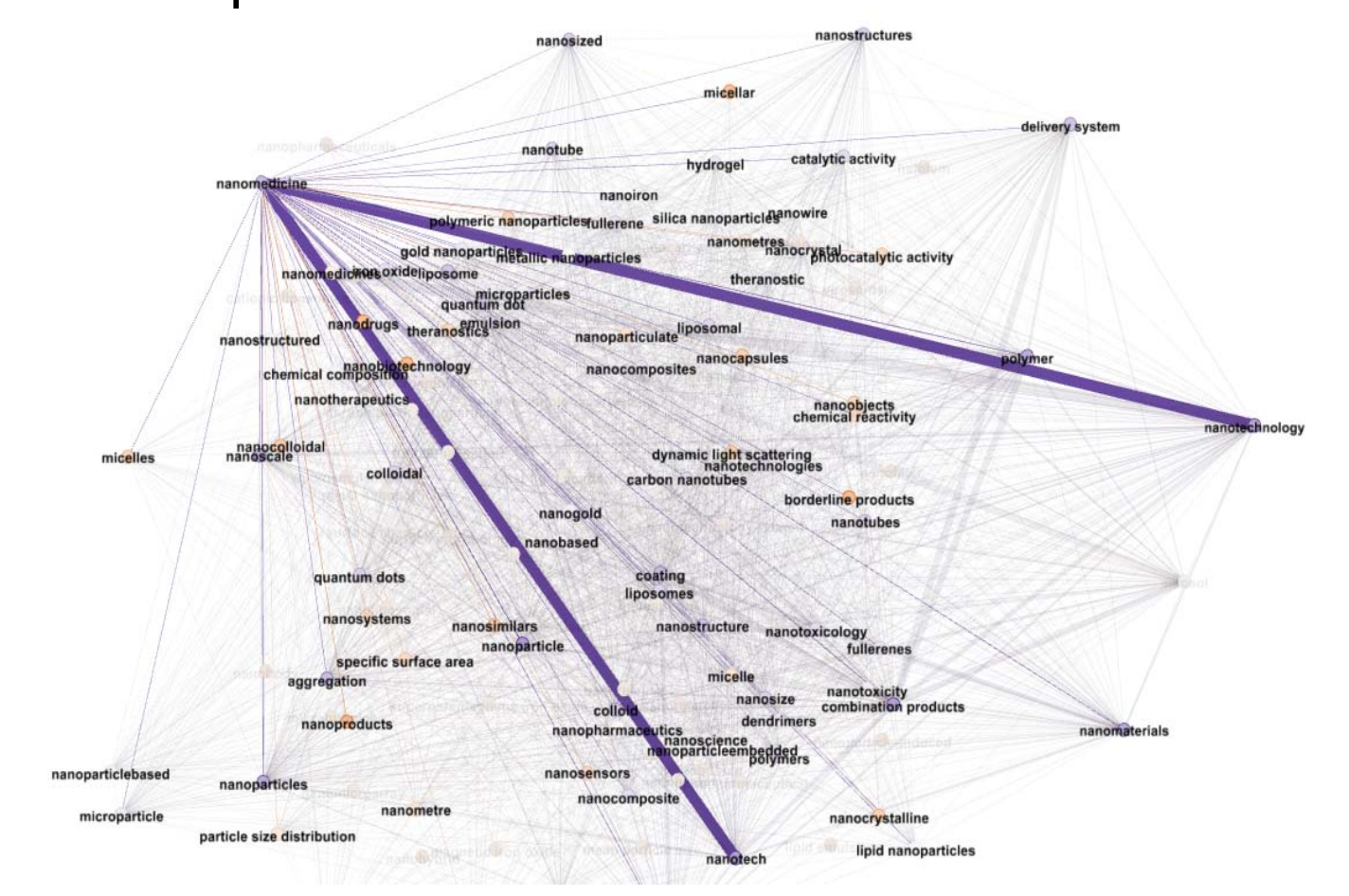


Figure 3 Nanomedicine terms regulatory authorities' websites. This term network reflects the complexity of the nanomedicine terminology in regulatory websites. The edge-weights reveals few strong correlations between terms suggesting a topic still in development.



A) Selected terms nationwide field by relevance

| Term | TGA Canada | Sacrobutel, Switzerland | HC Canada | US FDA | TW FDA | EMA | DO HEALTH | DO GROWTH |
|-----------------|------------|-------------------------|-----------|--------|--------|-----|-----------|-----------|
| Antibiotics | 106 | 112 | 135 | 33 | 33 | 33 | 33 | 33 |
| Anticoagulants | 25 | 81 | 105 | 25 | 63 | 63 | 63 | 63 |
| Nonsteroidal | 17 | 0 | 330 | 54 | 2 | 123 | 33 | 33 |
| Anticancer | 4 | 483 | 67 | 139 | 4 | 26 | 26 | 26 |
| Radio | 3 | 34 | 26 | 335 | 0 | 37 | 36 | 36 |
| Chemical | 4 | 29 | 3 | 184 | 7 | 104 | 3 | 3 |
| Mineralogy | 17 | 0 | 221 | 430 | 35 | 2 | 34 | 33 |
| Anticancerology | 20 | 24 | 22 | 21 | 61 | 60 | 2 | 2 |
| Anticancer | 15 | 0 | 7 | 6 | 5 | 4 | 3 | 0 |
| Anticancer | 6 | 0 | 6 | 5 | 2 | 1 | 4 | 2 |
| Anticancer | 1 | 12 | 1 | 2 | 0 | 385 | 0 | 0 |
| Anticancer | 1 | 0 | 1 | 23 | 23 | 0 | 0 | 7 |

B) Nonmedic terms in regulatory authorities websites

| Term | TGA | Switzerland | HAS | HC | US FDA | TW FDA | EMA | DO HEALTH | DO GROWTH |
|---------------|-----|-------------|-----|-----|--------|--------|-----|-----------|-----------|
| Epinephrine | 5 | 4 | 0 | 16 | 230 | 8 | 52 | 0 | 0 |
| Anticoagulant | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| Mineral | 5 | 1 | 0 | 6 | 7 | 37 | 3 | 0 | 1 |
| Chemical | 0 | 0 | 0 | 0 | 121 | 0 | 0 | 0 | 1 |
| Chemical | 3 | 0 | 0 | 21 | 32 | 6 | 0 | 0 | 1 |
| Chemical | 0 | 2 | 0 | 6 | 0 | 0 | 0 | 0 | 1 |
| Colloid | 47 | 62 | 1 | 34 | 234 | 0 | 4 | 1 | 1 |
| Chemical | 0 | 0 | 0 | 162 | 0 | 1 | 147 | 0 | 0 |
| Hydrogel | 13 | 349 | 0 | 20 | 81 | 0 | 0 | 0 | 0 |
| Chemical | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 |
| Emulsion | 91 | 3601 | 0 | 47 | 239 | 22 | 33 | 0 | 20 |
| Nanomedicine | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |

Figure 4 Regional terminology variability: most relevant top terms and nanomedicine . A) This graph shows regional differences in term occurrence frequencies and variability; some terms are region-specific. B) Regional term variability related to nanomedicines suggests regional differences in number of applications, and nanomedicine products approved or under investigation.

- Tech and text mining tools are suitable methods to obtain an objective picture on the terminology used in the nanomedicine field and relevant keyword extraction.
- Training keyword set matching and term co-occurrence networks reveal differences between terminology used in the literature and regulatory authorities
- Regional differences are reflected in the number and type of terms used in regulatory documents.
- *Nanomedicines* is a term mainly used in Europe which can create confusion or ambiguity in the international communication among stakeholders.
- Complexity, diversity of terms, and their correlation elucidate the challenges of communication in biomedical research and regulation of nanotechnology-based products.

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Disclaimer: "The views expressed are solely of the writer and may in no case be seen as stating an official position of the European Commission."

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