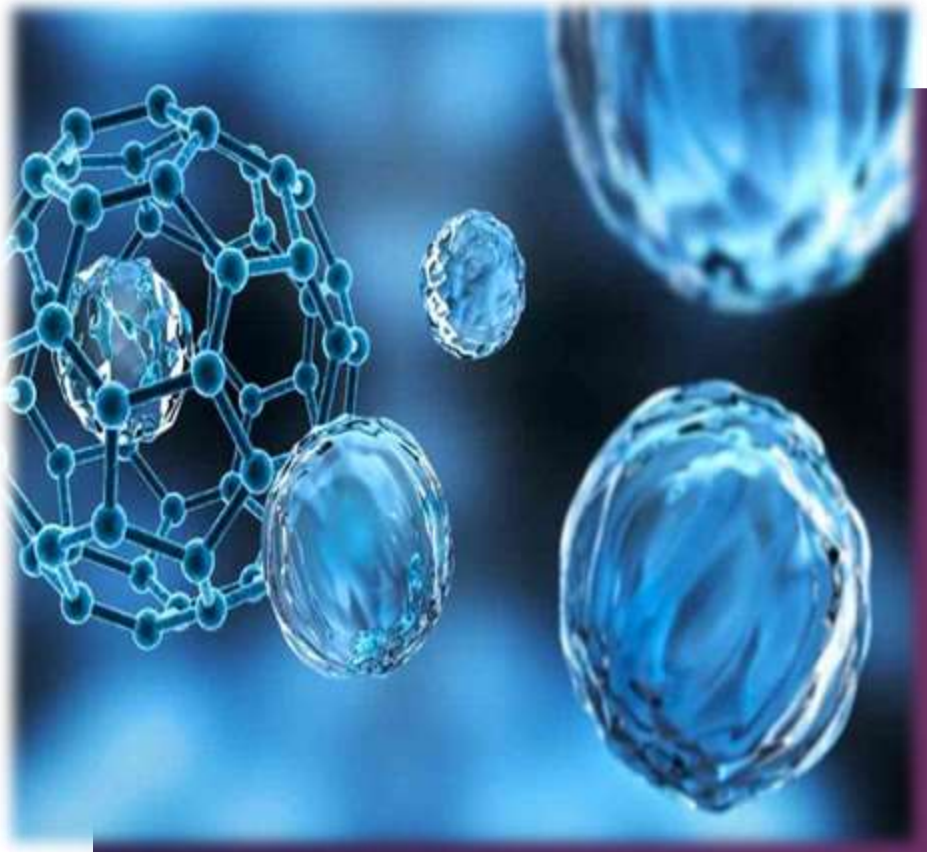

ERA4Health Partnership

Fostering a European Research Area for Health

VÝROČNÍ
VĚDECKÁ KONFERENCE
CZECRIN

ERA4Health Partnership

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MARTA DEL ALAMO (ECRIN)

ERA4Health: Overview

Co-funding Joint Transnational Calls

ERA4Health Pillar 2B IICS

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ERA4Health: Approach and objectives

This Partnership brings the opportunity to **increase European collaborative research funding** by creating a **funding body for joint programming** in priority areas addressing **European Public Health Needs** and set up Europe at the forefront of science and innovation in Health Research by 2050.

SO1. Support relevant medical research including clinical fields and intervention areas (prevention, diagnosis, treatment)

SO2. Improve the utilisation of existing health technologies in clinical practice

SO3. Build capacity, in particular in conducting IICSs at European scale

SO4. Implement and develop RRI in multiple ways (Partnership operationalization, calls, in project evaluation and monitoring)

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ERA4Health: the context

- Majority of **European investments** in biomedical and health research belongs to **MS**
- Only **10%** of the overall European budget for biomedical and health R&D is considered **collaborative research** (from Framework Programme and European Partnerships)
- Council adopts conclusions on **new ERA**: commit 5% of national public R&D funding to joint programmes and European partnerships by 2030
- 80% of partners (funders) in European Partnerships are the same (**duplication**)
- Number and thematic of European Partnerships are **limited**
- **New EU Clinical Trial regulation**: low-intervention clinical trials

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ERA4Health: Working plan

- Flexible instrument for joint programming in European priority areas
- Partners: research and innovation funding organisations (national, regional, MS, AC, TC)

Phase 1

- Integrate existing initiatives and launching transnational calls in **nutrition, diet and healthy life styles, cardiovascular diseases and nanomedicine**
- **Establish a framework to support multinational Investigator Initiated Clinical Studies (IICSs)**
- Duration: 2 years

Phase 2

- Calls in priority areas
- Calls for IICS in Health Technologies addressing public health needs
- Duration: 5 years

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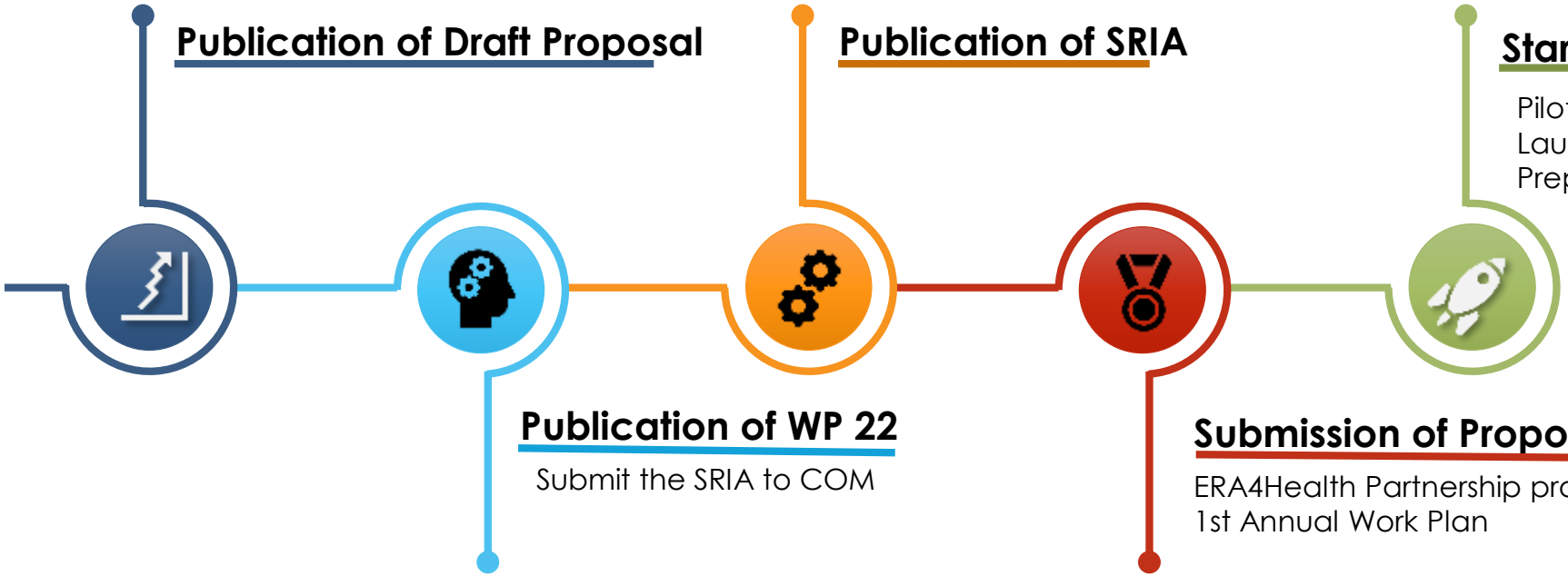
ERA4Health: preparation timeline



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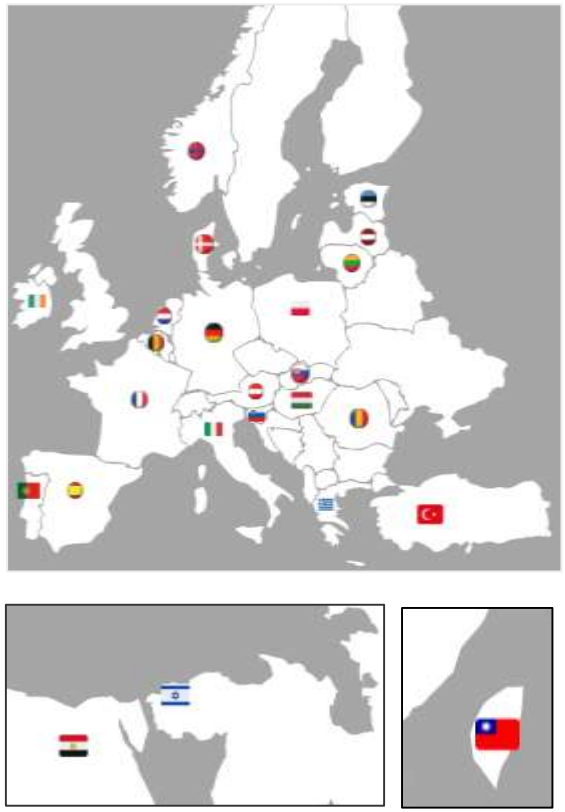
ERA4Health Consortia



- **32 Funding Organisations** covering:
  - 20 of the actual 27 members of the European Union
  - 3 Third Countries associated to Horizon Europe (Israel, Norway, Turkey)
  - 2 Third countries (Egypt, Taiwan)

- **Different type of Funding Organisations**:
  - basic research
  - applied/translational research
  - clinical research
  - Mixed type of research

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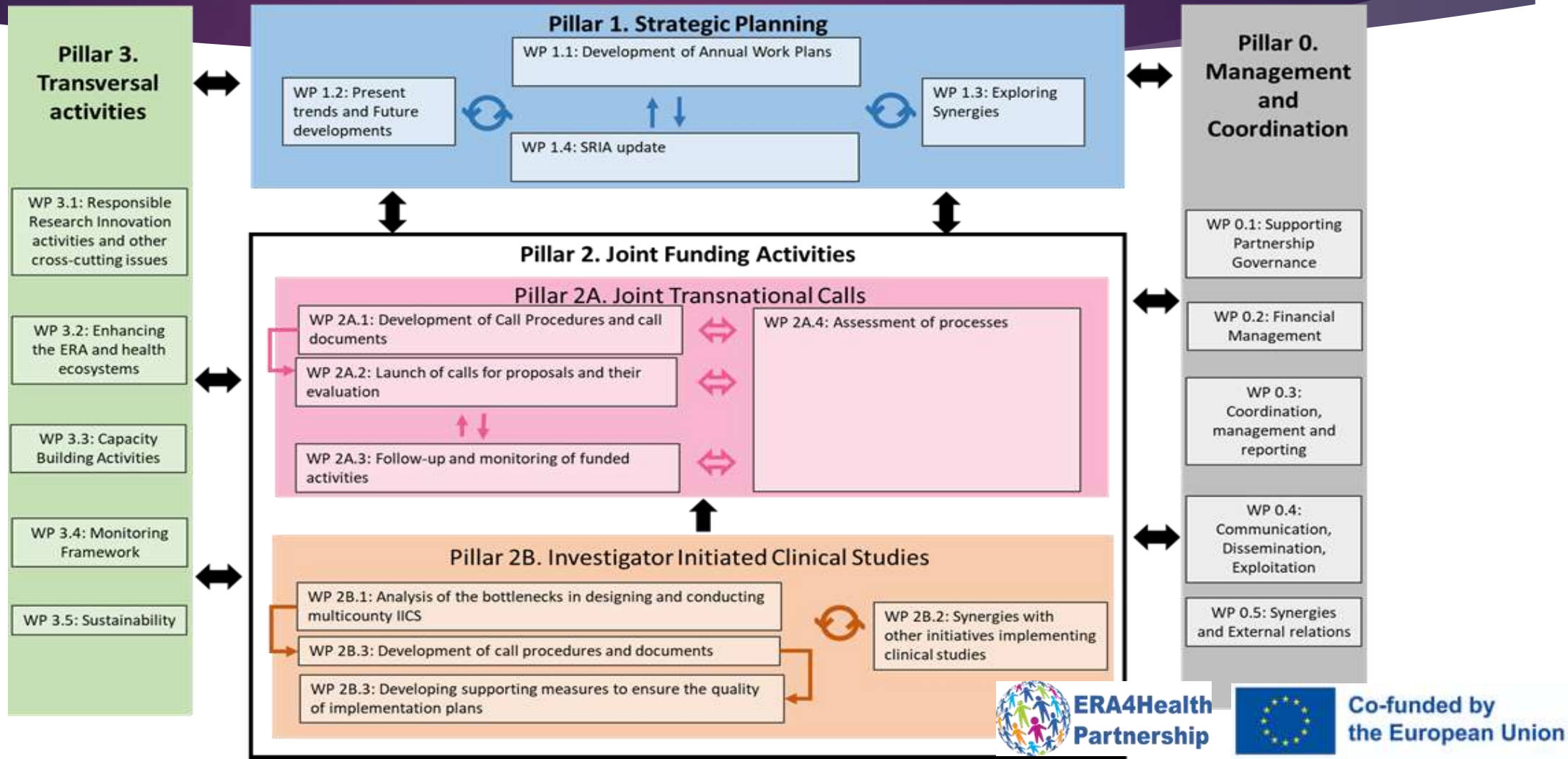
ERA4Health Project Structure



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ERA4Health Synergies

- The potential synergies of ERA4Health with other initiatives are:
  - **EU funding programmes**: based on EU policies that will help define a relevant approach within each specific area and research priorities.
  - **ERANETs/Joint Programming Initiatives (JPI)/European Joint Programme (EJP)/Partnerships**: close collaboration will be promoted with these initiatives in terms of peer-learning and research priorities selection. For each annual programme elaborated by ERA4Health, a deep analysis and exchange of information will be carried out to avoid doubled funding. Besides that, an analysis of complementarities among funded projects will be carried out to foster connections among the consortia funded.
  - **Other EU funding instruments**: information on complementarities with research priorities will be exchange to avoid duplications.
  - **EU co-funding instruments**: promotion of regional/national complementarities with EU co-funding instruments to leverage EU funding.
  - **European Research Infrastructures**: ECRIN, BBMRI, ELIXIR, INFRAFRONTIER, INSTRUCT, EATRIS, EU-OPENSCREEN, EuroBioimaging, ERINHA, etc
  - **EOSC** The European Open Science Cloud

ERA4Health Priority Research Areas

- 4 High Priority research areas

1. **Prevention and Public health strategies**
2. **Nutrition- and lifestyle-related diseases**
3. **Cardiovascular diseases**
4. **Nano and advanced technologies for disease prevention, diagnostic and therapy**

- Room for flexible funding topics e.g. Transversal approaches towards a better disease prevention, diagnostics and treatment, biomedical research domains not well covered, Intervention areas focused on target groups

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Co-funding Joint Transnational Calls

- Joint Transnational Calls (JTCs) allows a collaborative research creating **complementary transnational research consortia** with an added value.
- If it is a cofunded JTC, appart from the national/regional financial contribution, it will be added the **co-funding by the EC (usually 30%).**
- **Distribution of co-funding** among the different funders: different options.
- To optimise regional/national and the EU contributions, first it should be explored all funding **solutions to unblock situations** at the regional/national level.
- **National funding should be adequate** with the expected success of their respective research communities, if possible by increasing their budget.

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Co-funding Joint Transnational Calls

- . Regular rules for **co-funding distribution in Joint Transnational Calls**:
  I. Reimbursement: 50%-70% of the EU Top-Up for **just-retour reimbursement**.
  II. Gap filling: 30%-50% of the EU Top-Up for **Gap filling**.
  III. A Funding Organization **cannot receive more than 20%** of the EU Top-Up total budget.
  IV. The total EU Top-Up received by a single Funding Organization **shall not exceed the respective national/regional contribution** provided to research projects
- Other potential options for **co-funding distribution in Investigator Initiated Clinical Studies** (IICS), since this option presents several problems for IICS.
- These options will be explored in **ERA4Health in Pillar 2B** dedicated to set up the framework to support multinational Investigator Initiated Clinical Studies (IICS).

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ERA4Health Pillar 2B IICS

- Analysis of the **bottlenecks and challenges** in designing and conducting multicountry IICS
  - **Regulatory and ethical ecosystem** and risk-based oversight, taking into account the objective of the study,
  - Contracting between sponsors and investigation sites, insurance and indemnification, the adverse event reporting, the use of **risk-based monitoring** strategies,
  - **Data management** and data sharing issues, management, manufacturing and labelling of Investigational Medicinal Product (IMP) and placebo.
  - Site selection and **patient recruitment** strategy, cost evaluation, **flexibility in budget allocation** will also be considered.

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ERA4Health Pillar 2B IICS

- Identifying the **challenges raised by clinical trials** funded through a virtual common pot
  - **National funding agencies** for clinical trials involved
  - Project **timelines** (5 years ?), flexibility in duration, no-cost extensions
  - **Level of funding** ? 2-6M€ ? Promote pragmatic trials ?
  - Flexibility in **budget allocation** (based on actual recruitment)
  - Flexibility in the **consortia** (new partners addition)
  - Flexibility in site activation or closure, **investigation sites** = subcontractors ?
  - Support by **dedicated research infrastructure** (ECRIN, c4c, ECRAID, EORTC etc)

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ERA4Health Pillar 2B IICS

- Mapping of **funding sources available** to fund multicountry IICS in Europe, including:
  - National funding organisations allowing **cross-border funding** for IICS,
  - Initiatives based on **common pot** mechanisms,
  - Multinational **charity funding**,
  - Funding through the **central EU budget** of the Horizon Europe programme,
  - Other **virtual common pot schemes**, including the ERA-Net and partnership mechanisms

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ERA4Health Pillar 2B IICS

- **Eligibility criteria** for supported IICS to be defined:
  - **Multinational study**, run in at least 3 countries?
  - Any **medical field**, or some diseases / patient populations excluded?
  - Only **interventional, or** also **observational**?
  - Any **intervention** (diagnostic, prevention, therapeutic)?
  - Any **phase**? or phase I excluded?
  - On **health products** and procedural intervention? biotherapy and regenerative medicine?
  - Which **types of trials** should be allowed or excluded?

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ERA4Health Pillar 2B IICS

- **Selection process** : one or two steps
  - 1 - science and public health value
  - 2 - feasibility / logistics / regulatory / recruitment / timelines / budget / unnecessary investigation / quality

- **Objective of the supported trials** compatible with pragmatic design:
  - Repurposing trials (HTA / EMA)
  - Comparative effectiveness / optimisation

- Consider adaptive **platform trials** and allows **international cooperation**

- **Possible role of COFUND**
  - Increase level of funding, leverage effect for national funding bodies
  - Funding research infrastructure support, and sponsor
  - Flexibility in budget allocation

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ERA4Health Pillar 2B IICS

- Further activities related with **IICS framework development**:
  - Developing supporting measures to ensure the **quality of implementation plans**
  - Preparation of **template documents** supporting the calls for multinational IICS
  - Procedure for funding IICS under **health emergency**
  - **Monitoring procedure** during the conduct of the funded IICS
  - **Mapping of organisations** supporting the planning, design and conduct of multicountry IICS at national and European level
  - Establishment of a **coordination and liaison mechanism.** A multicountry IICS coordination board will be set-up jointly with Pillar 1

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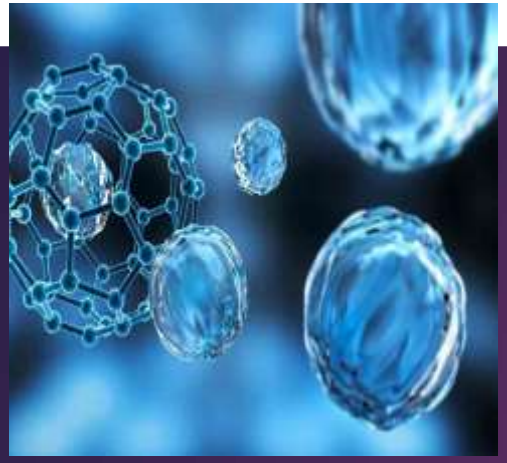

Thank you

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