

ECRIN, infrastructure for multinational clinical trials in Europe

Authentication and authorization infrastructure needs

www.ecrin.org



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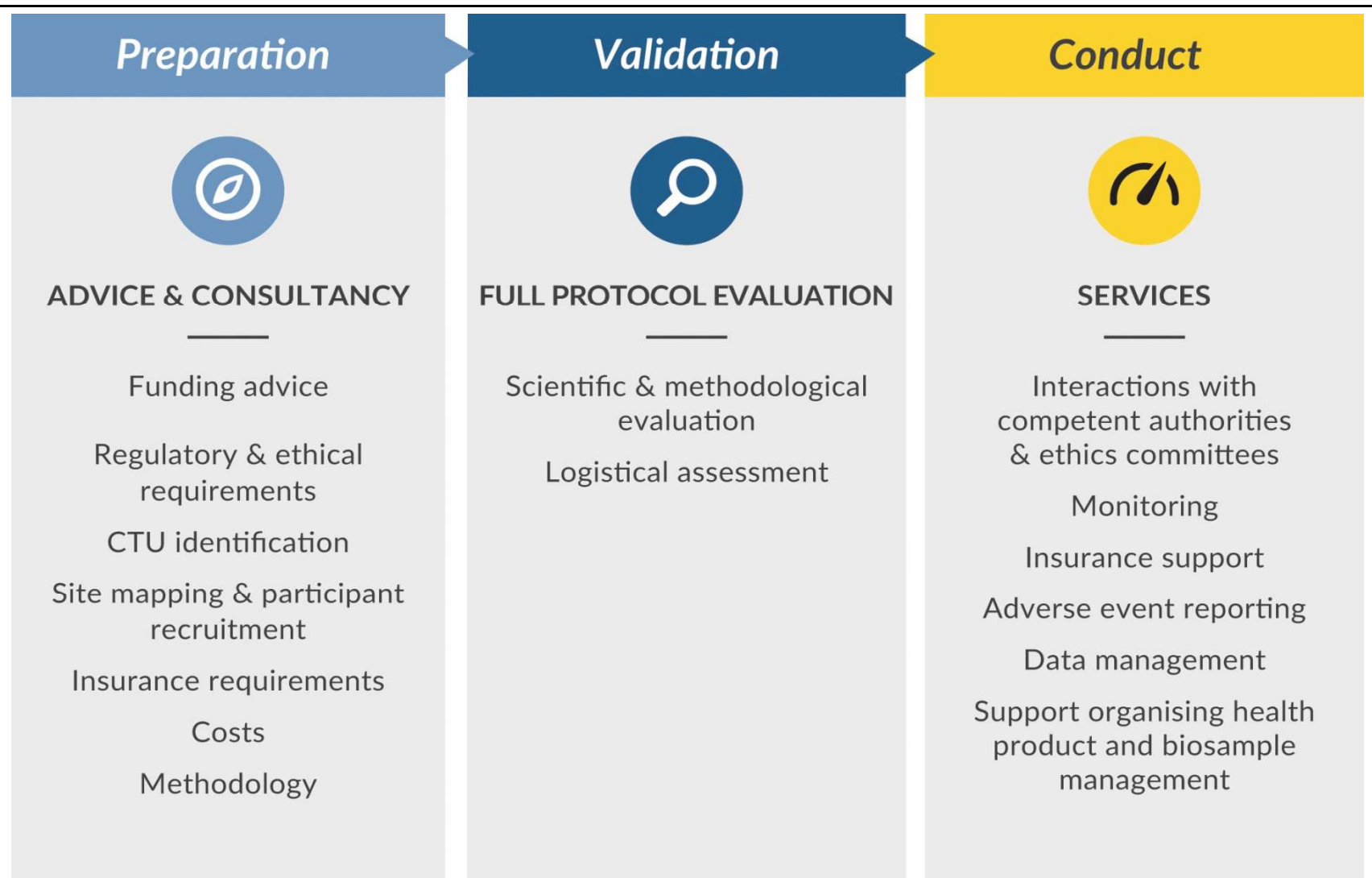
ECRIN, infrastructure for multinational trials



- **Mission:** support the conduct of multinational clinical trials across Europe
- **Services:** operational services to sponsors in the **management of multinational trials** : regulatory and ethics, adverse event reporting, monitoring, data management etc.
- **e-services** : access to tools (ex. regulatory database)
- **Access** to individual patient data : CORBEL WP3.3

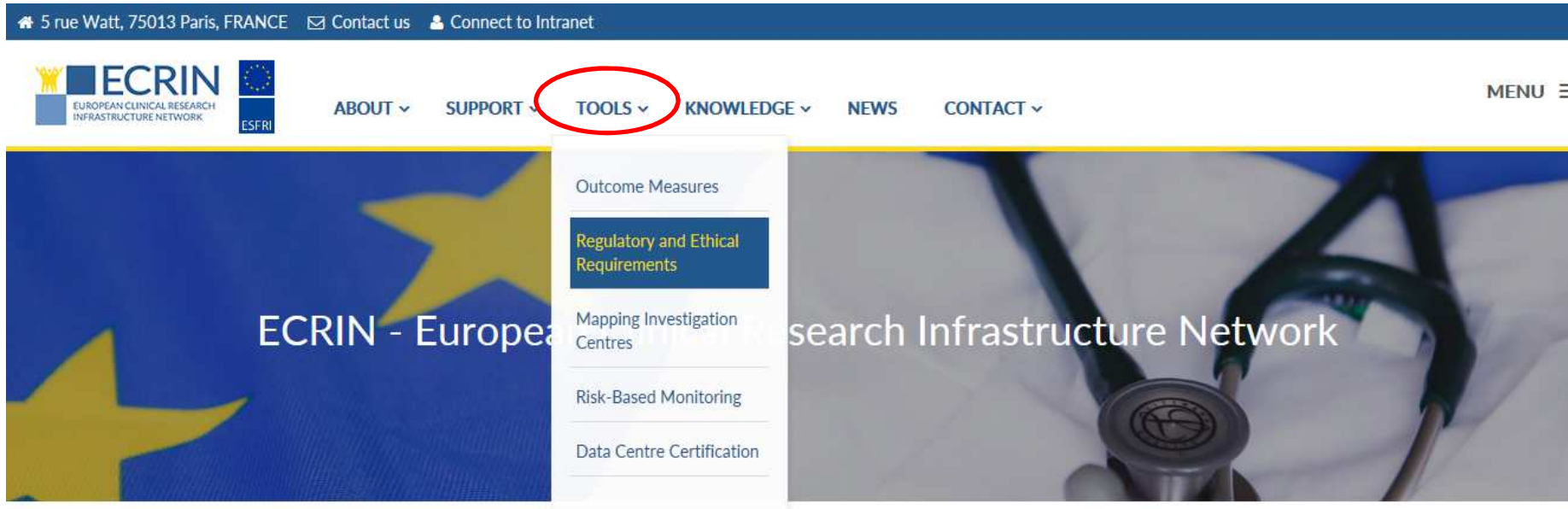
Operational support to clinical trials

Services at non-profit cost for the management of multinational trials



Capacity : Tools for multinational trials

ECRIN Provides and Maintains Tools to Facilitate Research and Trial Organisation (see www.ecrin.org)



- Quality assurance / SOPs
- Data centre certification
- Regulatory and ethical database
- Methodology guidelines

- Outcome measure database
- Risk-based monitoring toolbox
- Mapping of investigation sites
- Training
- Communication



Authentication and authorization infrastructure needs

- E-services ? open / restricted access ?
 - Mapping sites, CTUs, quality documents etc.
- Access to individual patient data
 - Requirement = eligibility criteria
 - CORBEL WP3.3
 - Challenge : anonymisation, personal data protection, etc
 - Procedure : group consensus
 - IT solution ?
 - Controlled access

