Clinical Safety services.

**Establishment and maintenance,
case management, safety reporting.**

Clinical Safety.

Arriello's Clinical Safety services can provide a faster, better, smarter solution to your setup, documentation, reporting, submission and ongoing trial management needs.

The outsourcing of a wide range of Clinical Drug Safety activities and guidance is now a widely accepted, approved and in-demand practice.

To bring our years of expertise, reputation and **faster, better, smarter** service ethos to this fast-growing area, Arriello has created a significant investment and development program in Clinical Safety services to meet the needs and expectations of current and prospective clients, such as sponsors and CROs that run clinical trials.

Establishment and maintenance of sponsor drug safety projects.

At the start of your trial, we can provide a range of setup services to make the whole process **faster, better, smarter**. A correctly set up project can save you time, money and ensure that all the phases of the trial are robust and efficient.

EV Responsible Person.

24/7 drug safety contact point.

Creation of reporting instructions for clinical centers.

Drug safety and reporting training.

Clinical trial documentation review.

Safety management reporting plans – preparation and review.

EudraVigilance Clinical Trial Module registration.

Case management.

We work alongside the assessments from your Clinical Trial Principal Investigator, and together with our own assessments, process all documentation and safety database entry. We also handle all authority submissions and ethic committee communications on your behalf.

SAE/SUSAR processing.

MedDRA coding.

Global Safety Database management.

Aggregate/annual safety reports and other services.

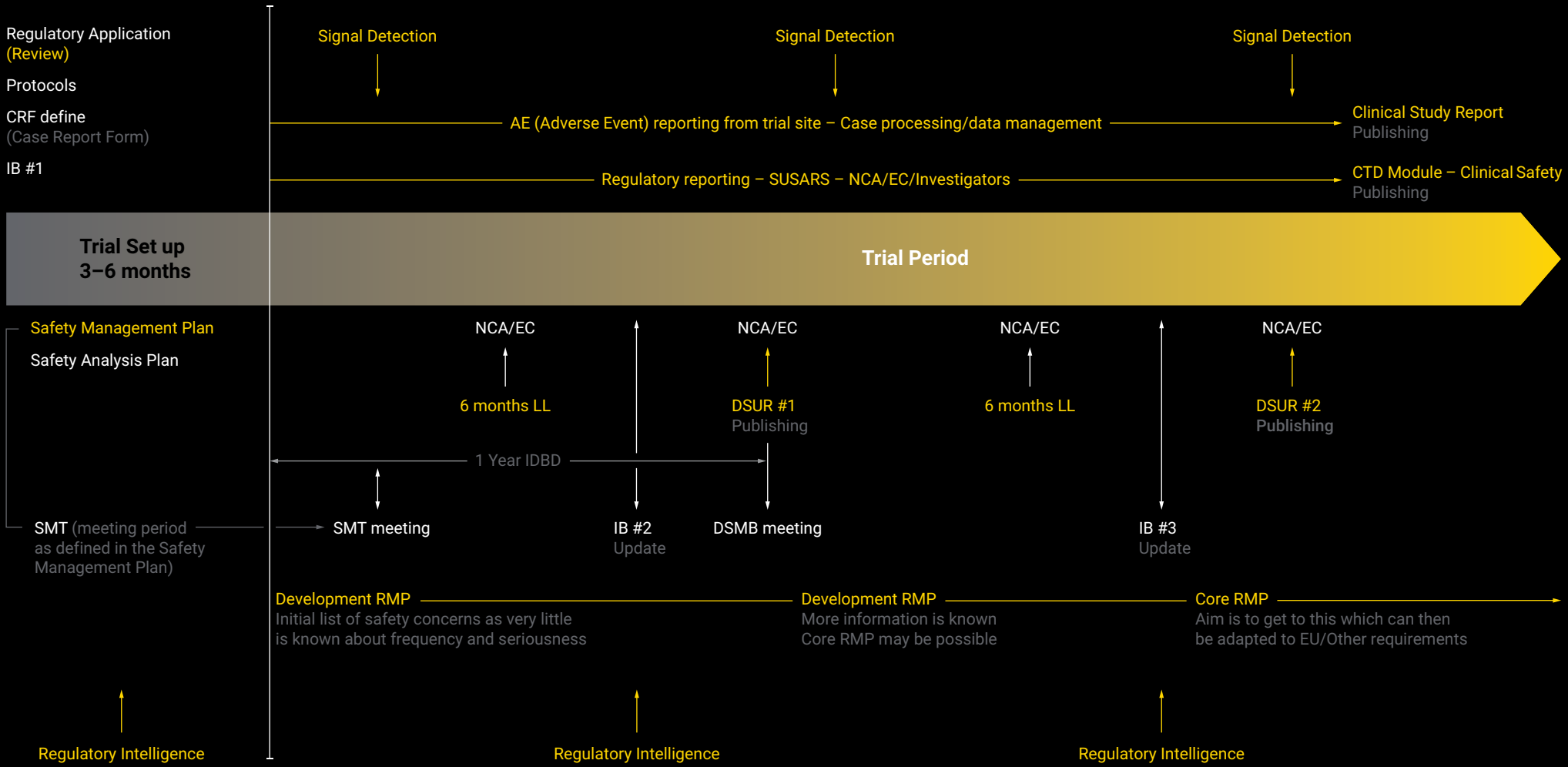
Whatever your safety reporting needs throughout the duration of your trials period, we can handle it, **faster, better, smarter**.

DSUR processing.

Submissions and documentation.

The clinical trials timeline.

Arriello offers Clinical Safety services in the areas marked in yellow.



IB	Investigational Brochure includes Reference Safety Info
NCA	National Competent Authority
EC	Ethics Committee
LL	Line Listing
DSUR	Development Safety Update Report (Annual)
RMP	Risk Management Plan
SMT	Safety Management Team meeting
IDBD	International Drug Birthday Date
DSMB	Data Safety Monitoring Board (Independant)

from development to market.
faster. better. smarter.

arriello

About us.

Arriello has been a leading provider of risk management and compliance services to the Life Sciences sector since 2008.

These include Market Consultancy, Global Regulatory Affairs strategy and implementation, Full and Local Pharmacovigilance solutions, Clinical Drug Safety, and Quality and Compliance auditing and systems.

Our brief is simple; to make the process from development to market faster, better and smarter.

Headquartered in Ireland, with European operations in Central Europe, we provide expert Market Access guidance across the EU, US, LATAM, CIS, MENA, Asia and South Africa.

With our extensive global vendor network, ISO 9001 certification, years of experience and satisfied clients, including Global Originators, Biotechs, Generics and CROs, you can be confident in our ability to deliver.

However complex or simple your requirements, you can rely on us as a trusted partner.

Global headquarters
Arriello Ireland Limited
No. 51, Bracken Road
Sandyford, Dublin D18 CV48
Ireland
Phone: +353 1 293 6755

European operations
Arriello s. r. o.
Olivova 2096/4
110 00 Prague 1
Czech Republic
Phone: +420 222 367 765

USA office
Arriello USA
One Marina Park Drive
Suite 1410
Boston, MA 02210
USA
Phone: +1 617 807 7016

E-mail: info@arriello.com
linkedin.com/company/arriello_group

www.arriello.com