

## Main skills

- › Clinical Evaluation and Clinical investigations of medical devices, Good Clinical Practices ISO 14155
- › In depth knowledge of Regulations and Standards for Medical devices, with an active involvement in writing standards.
- › Building networks of medical experts, investigators, scientific societies, patients' organizations, and regulatory specialists.
- › Scientific, medical, and regulatory watch.
- › Team player

## Medical Advisor / Medical director

- 09/2018—now › **Director, Medical and Regulatory affairs, [Ceraver Osteal](#)**, Roissy, France, part-time: Orthopedic class III implants. Supervises all clinical and regulatory activities, including transition to Regulation 2017/745 UE. Defines, plans, and implements clinical, regulatory, and market access strategies including pre and post market clinical investigations. Organizes clinical evaluation activities, scientific watch. Liaison with R&D and Marketing/Sales on all medical/regulatory aspects. PRRC (Person responsible for Regulatory compliance). Internal auditor.
- 06/2014—now › **Consultant, Clinical affairs, Savoir-Faire Ad'Missions, [TechMD.fr](#)** team, part time since 09/2018, Medical, regulatory and market access support to medical technologies companies : establish Clinical strategy and integrate clinical/preclinical evidence with regulatory and market access requirements along the entire device lifecycle → *support of 50+ companies for their clinical & regulatory strategy, incl. 150+ clinical evaluation reports : classes I to III, incl diagnostic, software, and combination device, MDD and MDR and clinical audits.*
- 2001—2013 › **Scientific & medical Director, [Fondation de l'Avenir, \(Mutualité Française\)](#)**, France, medical & surgical research: Evaluate all research and innovation projects (150/y). Build a network of ca. 600 experts in medical technologies. Provide methodological & regulatory support for clinical studies (15-20/y). Supervise large animal ([CERA-IMMR](#)) and health economics research ([DIES](#)) sponsored by the Foundation. Direct contact with private donors on medical subjects. Responsible for medical marketing contents incl. lay public. → *support of over 500 innovation projects + consultancy on new techs and e-Health for "Mutualité Française"*
- 05—12/2000 › **Medical and editorial manager, [Websurg.com](#), [Ircad](#)**, Strasbourg, surgical e-learning, Manage a team of 15 medical writers, translators, and illustrators and coordinate surgical experts from 12 countries. Define editorial lines with surgeons (videos, interviews, interactive illustrations...). Supervise edition & translations → *In 7 months, we finalized 100+ cross-media contents in 3 languages and launched the site.*
- 1994—2000 › **Senior manager, medical technologies research, [APHP DRRC Île-de-France](#)**, Paris (part time-1994-1998) Fully responsible for organizing clinical and pre-clinical research activities in surgery, medical technologies and Imaging/Radiology, for all hospitals in the Paris area, incl. supervision of 4 large-animals facilities for surgical research. → *Created a 15 persons clinical research team (engineers, CRAs, project managers) including a medical devices regulatory/vigilance unit. Supervised more than 100 clinical trials on surgery and devices, including audits.*

## Physician

- 1986-1998 › **Resident, Chief Fellow and Staff physician, Paris-area Hospitals [AP-HP](#)**: Internal Medicine (Endocrinology) then Medical Imaging- Conventional Imaging (all modalities) with focus on ENT, Neuroradiology, Interventional & Vascular imaging → *Developed Clinical Research, and pioneered a local medical devices vigilance system.*

## International standardization (since 1991)

As Convenor: › [CEN TC205 WG16](#) "Catheters" (since 2017-), [CEN BTF 123](#) "Luer Connectors" 2001-2007

As Expert: › [CEN/CLC JTC3 & ISO TC 210](#) "Quality management and corresponding general aspects for medical devices", [ISO/TC 194/WG4](#) "Clinical Investigations of medical devices in Human"

## Teaching

- 2016—now › [IFIS-DM](#): "Clinical Evaluation of medical devices" & "Clinical Investigations- GCP ISO EN 14155" - for the industry
- 2009—2016 › [UPEC University](#) "Innovation and Research in Healthcare" – University Master2 in Healthcare Management
- 2009—2012 › [Ecole Supérieure Montsouris-ESM](#) "Risk management & Morbidity Mortality Reviews for health professionals"
- 2003—2009 › [University Paris 7 Diderot](#) "Regulation and standardization of medical devices", post-graduate diploma
- 1994—2013 › [Universities Paris Diderot, Paris Sud and UPEC](#) : Methodology, Regulations, and Ethics of Clinical research

## Learned societies and other expert activities

- 2023... › Expert for [BPI France](#) (French agency and Public Bank for innovation) : Imaging, AI, medical innovations
- 2015-2019 › Member of the [French Radiological Society](#) innovation think tank, coauthor of a Whitepaper on AI (2018)
- 2001 – 2015 › ad-hoc Expert for the French medical safety agency ([ANSM](#)) in the field of Medical Devices safety
- 2003-2006 › External member of the Scientific Counsel of [Dental faculty, Paris-Garanciere](#)
- 1989 › Founding member of [CIREOL](#) (French Society for ENT Imaging teaching and research)

## Education

- 1998 › [HEC School of Management](#): Management of Hospitals and Clinical Research (in-house, APHP – 160h)
- 1996 › [PhD](#) in the Life Sciences (Medical Imaging/ Biomaterials), University Paris 11 Sud / Risks of Catheters
- 1991 › [MD](#) Medical Doctorate, University Paris 7 Diderot, specialty: Medical imaging & Radiology / Interventional
- 1990 › [CESAM](#) Medical Statistics applied to clinical research (STARC), University Paris 7 Diderot
- 1987 › [FMGEMS](#): ECFMG / US Foreign Medical Graduates Examination / passed: Basic Sciences, English & Medicine
- 1983 › [DULAP](#) : University Diploma, applied English, cum laude.

## Languages and Computers

**French**: native language, **English**: Fluent, level C2

**German** : Professional capacity **Spanish** : basic professional capacity.

**Computers**: Office suites / Databases creation and management/ Statistics /Bibliographic software/ Image processing

## Other activities / Community involvement

- female football club officer (Club Athlétique Paris 14) (2016-2020) – logistics and team support.
- president of a parent's association, school board elected (2013-2016).

## Scientific publications

1. SFR-IA Group, CERF, for the French Radiology Community. Artificial intelligence and medical imaging 2018: French Radiology Community white paper. Diagnostic and Interventional Imaging. 2018 Nov;99(11):727–42. [DOI : 10.1016/j.diii.2018.10.003](#)
2. Gelb AW, Mainland P, Phillips P, Sharpe P, Kinsella SM, Bailly A-L, et al. J'agis! Anesth Analg. 2016 Sep;123(3):798–9. [DOI : 10.1213/ANE.0000000000001428](#)
3. Castel-Molières M, Cuaz-Perolin C, Bailly A-L, Lafont J, Neuville S, Thiveaud D. [Enteral feeding devices safety]. Nutrition Clinique et Métabolisme. 2015 Dec;29(4):226–33. [DOI : 10.1016/j.nupar.2015.09.004](#)
4. Laurent A, Durussel JJ, Dufaux J, Penhouët L, Bailly AL, Bonneau M, et al. Effects of contrast media on blood rheology: comparison in humans, pigs, and sheep. Cardiovasc Intervent Radiol. 1999 Jan;22(1):62–6. [DOI 10.1007/s002709900330](#)
5. Bailly AL, Lautier A, Laurent A, Guiffant G, Dufaux J, Houdart E, et al. Thrombosis of Angiographic Catheters in Humans: Experimental Study. The International Journal of Artificial Organs. 1999 Oct;22(10):690–700. [DOI 10.1177/039139889902201007](#)
6. Durussel JJ, Dufaux J, Laurent A, Penhouët L, Bailly AL, Bonneau M, et al. Comparative viscosity and erythrocytes disaggregation shear stress of blood-radiographic contrast media mixtures in three mammalian species. Clin Hemorheol Microcirc. 1997 Aug;17(4):261–9. [PMID 9493892](#)
7. Penhouët L, Laurent A, Dufaux J, Bailly AL, Durussel JJ, Bonneau M, et al. Blood viscosity comparison and red blood cells aggregation in three species (human, pig, sheep) before and after addition of contrast medium. STAL-AGRI (France). 1996; [Google Scholar](#)
8. Bailly A-L. [Physical and biological characterization of intravascular catheters and risks associated with their use ] (University Doctorate thesis). University Paris 11; 1996. [SUDOC ID : 245618856](#)
9. Bailly AL, Laurent A, Lu H, Elalami I, Jacob P, Mundler O, et al. Fibrinogen binding and platelet retention: relationship with the thrombogenicity of catheters. J Biomed Mater Res. 1996 Jan;30(1):101–8. [DOI 10.1002/\(SICI\)1097-4636\(199601\)30:1%3C101::AID-JBM13%3E3.0.CO;2-R](#)
10. Cognard C, Gobin YP, Pierot L, Bailly AL, Houdart E, Casasco A, et al. Cerebral dural arteriovenous fistulas: clinical and angiographic correlation with a revised classification of venous drainage. Radiology. 1995 Mar;194(3):671–80. [DOI 10.1148/radiology.194.3.7862961](#)
11. Bailly AL, Penhouët L, Laurent A, Dufaux J, Domas L, Merland JJ. An hydrodynamical study of iodized contrast media intravenous injection through micro catheters. Journal de Radiologie (Paris). 1995;76(10):702. [Google scholar](#)
12. Durussel JJ, Guiffant G, Dufaut J, Bailly AL. [Experimental and theoretical study of thrombosis kinetics in angiographic catheters]. Journal Des Maladies Vasculaires. 1994;19:238–238. [Google Scholar](#)
13. Gobin YP, Houdart E, Rogopoulos A, Casasco A, Bailly AL, Merland JJ. Percutaneous transvenous embolization through the thrombosed sinus in transverse sinus dural fistula. AJNR Am J Neuroradiol. 1993 Oct;14(5):1102–5. [PMC 8332780](#)
14. Domas L, Laurent A, Wassef M, Bailly A, Beaujeux R, Merland JJ. [Morphological analysis and shape index of embolization particles]. Innovation et technologie en biologie et medecine. 1993;14(4):436–48. [Google Scholar](#)
15. Domas L, Laurent A, Wassef M, Bailly AL, Merland JJ. A simple method for morpho-analysis of embolization particles. In: Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE. IEEE; 1992. p. 2235–6. [DOI 10.1109/IEMBS.1992.5762253](#)
16. Domas L, Laurent A, Guichard JP, Bailly AL, Merland JJ. A study model for artefacts caused by Implantable materials in magnetic resonance imaging. In: Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE. IEEE; 1992. p. 1985–1985. [DOI: 10.1109/IEMBS.1992.5762132](#)
17. Bailly AL, Laurent A, Guiffant G, Dufaux J, Merland JJ. Thrombogenicity of angiographic catheters: Comparative and rheological study on human blood ex vivo in angiographic conditions. In: Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE. IEEE; 1992. p. 484–5. [DOI 10.1109/IEMBS.1992.5761071](#)
18. Bailly AL, Debout J, Laccoureye O, Laurent A, Merland JJ. Mechanical properties of catheters: Designing of tests for kinking, traction, and torsion and their validation on a series of central venous catheters. In: Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE. IEEE; 1992. p. 1162–3. [DOI 10.1109/IEMBS.1992.5761432](#)
19. Bailly AL, Williams M, Mattozza F, Guichard JP, Tubiana JM. [Imaging of the temporomandibular joint]. Ann Radiol (Paris). 1990;33(7–8):398–407. [PMID: 2095693](#)