

Rapport de stage d'application de DFASP2



Instituts
thématiques



Inserm



Institut national
de la santé et de la recherche médicale

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2 Liste des abréviations

HeTOP : Health Terminology/Ontology Portal

ANR : Agence Nationale de Recherche

AMM : Autorisation de Mise sur le Marché

MeSH : Medical Subject Headings

PMID : Pubmed Identifier

LIMICS : Laboratoire d'Informatique Médicale et d'Ingénierie des Connaissances en e-Santé

CISMeF : Catalogue et Index des Sites Médicaux de langue Française

CRBM : Constructeur de Requêtes Bibliographiques Médicales

RTU : Recommandations Temporaires d'Utilisation

PsyHAMM : Usage des médicaments Psychiatriques Hors Autorisation de Mise sur le Marché

ANSM : Agence Nationale de Sécurité du Médicament et des produits de santé

ARS : Agence Régionale de Santé

CHSA : Centre Hospitalier Saint-Anne

SIH : Système d'Information Hospitalier

ECMT : Extracteur de Concepts Multi-Terminologique

OnBaSAM : Ontology-Based Semantic Annotation Module

CIP : Code Identifiant de Présentation

CIS : Code Identifiant de Spécialité

UCD : Unité Commune de Dispensation

ATC : Anatomical Therapeutic Chemical Classification System

Inserm : Institut National de la Santé et de la Recherche Médicale

CHU : Centre Hospitalo-Universitaire

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5 Texte

5.1 L'Inserm

Créé en 1964, l'Institut National de la Santé et de la Recherche Médicale (Inserm) est un établissement public à caractère scientifique et technologique sous la tutelle du ministère de la Santé et du ministère de la Recherche. Il se consacre à la recherche biologique, médicale et la santé humaine. Il est le partenaire des plus grandes institutions engagées dans les défis et progrès scientifiques de ces domaines. L'Inserm est à l'origine de plus de 11 000 publications scientifiques. C'est le premier déposant de brevets à échelle européenne dans le secteur pharmaceutique et biomédical, 4^e dans le secteur des biotechnologies.

Il possède 281 unités de recherche, 36 centres d'investigation clinique et 34 unités de service en France. À l'étranger, il est associé à 29 laboratoires internationaux, possède 2 unités de recherche et représente plus de 6 000 coopérations avec des partenaires internationaux.

En 2008, l'Inserm crée 9 instituts thématiques dans les domaines suivants :

- Neurosciences, sciences cognitives, neurologie, psychiatrie
- Cancer
- Immunologie, inflammation, infectiologie et microbiologie
- Physiopathologie, métabolisme et nutrition
- Santé publique
- Technologie pour la santé
- Bases moléculaires et structurales du vivant
- Biologie cellulaire, développement et évolution
- Génétique, génomique et bio-informatique

Son président-directeur général est Gilles Bloch, sa directrice générale déléguée est Claire Giry.

5.2 Le LIMICS

Le Laboratoire d'Informatique Médicale et d'Ingénierie des Connaissances en e-Santé (LIMICS) est une unité mixte de recherche interdisciplinaire en informatique et informatique médicale. Il est placé sous cotutelle de l'Inserm, de l'université Paris Sorbonne et de l'université Paris 13. Le laboratoire possède différentes localisations géographiques mais reste centré sur l'Île-de-France. Il développe des approches innovantes de traitement de l'information de santé sur le plan méthodologique et applicatif afin que les systèmes d'informations s'intègrent mieux dans les activités décisionnelles de soins et de recherche.

Cette unité est composée de 38 membres permanents parmi lesquels des chercheurs Inserm, des enseignants-chercheurs en informatique et des médecins et pharmaciens hospitalo-universitaires. Le LIMICS a pour ambition de se positionner comme une des principales équipes européennes en e-santé. Par ses nombreuses collaborations nationales et internationales, le LIMICS a su développer sa notoriété. Il est à l'origine de travaux de recherche en Intelligence Artificielle portant sur la représentation des connaissances en santé, leur formalisation dans des systèmes d'apprentissage et l'analyse décisionnelle à partir de données biomédicales.

Les connaissances et solutions technologiques qui émergent de travaux du laboratoire ont pour but d'être exploitées dans des recherches appliquées, translationnelles ou cliniques en partenariat avec d'autres laboratoires de recherche, des partenaires industriels et des structures de soins. Le LIMICS est engagé sur différentes thématiques de recherche telles que la représentation et formalisation des connaissances, l'intégration et analyse de données de santé, l'aide à la décision, l'évaluation des pratiques ainsi que l'étude de l'impact des solutions proposées notamment son impact en médecine factuelle. La directrice du laboratoire est Marie-Christine Jaulent, le directeur adjoint est Stefan Darmoni.

5.3 Problématique du stage

Le projet PsyHAMM est un projet ayant obtenu une accréditation de l'Agence Nationale de Recherche (ANR) et concerne les maladies psychiatriques. Il a démarré en février 2019 et prendra fin en août 2021.

Les maladies psychiatriques sont une priorité de santé publique. Elles représentent près d'environ 20% des dépenses de santé et si l'on additionne les coûts directs et indirects, elles coûtent près du double des maladies neurologiques et neurodégénératives. Au niveau européen, cela représente 432 milliards d'euros [Gustavsson et coll, 2011]. Environ 30% des patients ne répondent pas ou très peu aux traitements ; ce qui témoigne d'un besoin de développer de nouvelles stratégies thérapeutiques. Ces dernières années, l'existence de formes frontières entre les catégories diagnostiques classiques, la remise en question de certaines catégories ainsi que de nouvelles pistes physiopathologiques sont apparues.

La psychiatrie est un des domaines médicaux qui prescrit le plus de médicaments pour des indications différentes de celles pour lesquelles ils sont mis sur le marché, en particulier en milieu hospitalier. C'est ce que l'on appelle une utilisation hors de l'autorisation de mise sur le marché (hors AMM). On peut citer à titre d'exemple, l'utilisation d'agonistes dopaminergiques dans la dépression résistante ou l'utilisation du Lorazepam dans des présentations particulières et graves de troubles psychotiques comme la catatonie. Deux autres types fréquents d'hors AMM sont la prescription en dehors de la tranche d'âge prévue et la prescription en dehors de la posologie autorisée [Brauner et coll, 2016]. Les raisons de la prescription hors AMM sont diverses. Dans certains cas, l'objectif est de répondre aux besoins médicaux non couverts. C'est alors une prescription de bon sens chez des populations peu ou pas étudiées dans les essais mais chez lesquelles une extrapolation de l'AMM est raisonnable. Dans d'autres cas, l'objectif est de trouver une solution thérapeutique dans des situations cliniques difficiles, en cas d'inefficacité ou d'effet insuffisant des traitements disposant de l'AMM.

Pour un certain nombre de ces cas, l'ANSM s'est dotée de recommandations temporaires d'utilisation (RTU). Ce dispositif encadre médicalement une utilisation hors AMM lorsque qu'il existe un besoin thérapeutique et que le rapport bénéfice/risque du médicament est présumé favorable, notamment à partir de données scientifiques publiées d'efficacité et de tolérance. Toutefois dans la pratique clinique, une majorité des utilisations hors AMM des médicaments n'entre pas dans le cadre de ce dispositif. Étudier l'ensemble des cas de prescription hors AMM est important pour les analyser et mieux comprendre leur motivation.

L'Agence Régionale de Santé (ARS) demande des actions d'analyse de ces prescriptions mais ce type d'étude est rendu difficile en l'état puisque les données ne sont pas directement disponibles dans une base unique et des formats exploitables. Le Centre Hospitalier Sainte-Anne (CHSA) et certains autres centres sont concernés par cette problématique. Un des points de travail important du projet PsyHAMM est également de retrouver automatiquement ces prescriptions.

Les objectifs du projet se découpent en un objectif final médical et deux objectifs « informatiques » liés à la modélisation et au développement d'outils d'ingénierie des connaissances pour arriver à capturer et traiter les données. Plus précisément, l'objectif médical du projet est :

- La constitution d'échantillons de patients au sein des services de soin du CHSA permettant le repérage et l'analyse des utilisations hors AMM de médicaments.

Du point de vue de l'ingénierie des connaissances, le projet vise 2 objectifs :

- La constitution de ressources sémantiques et de deux ontologies ; une décrivant les médicaments et leurs AMM et une autre qui concerne les maladies tout en respectant des formats standards (ceux du Web sémantique).

Par ailleurs, au sein du LIMICS est développé HeTOP, un moteur de recherche de connaissances médicales qui contient les principales terminologies médicales alignées les unes aux autres. Il permettra de mettre à disposition du projet d'autres terminologies adaptées aux sujets d'intérêt, les médicaments et surtout les maladies non psychiatriques.

- Le développement d'un outil de récupération et structuration de données nécessaire au repérage et à l'analyse des prescriptions hors AMM. Les prescriptions médicamenteuses sont disponibles dans le logiciel de prescription « Génois » du CHSA et les informations du patient sont disponibles dans le Système d'Information Hospitalier (SIH) de l'hôpital, Cortexte. Ce format textuel nécessite de développer un outil spécifique.

Le LIMICS est parti des outils d'ingénierie des connaissances qu'il a développés depuis plusieurs années, à savoir l'ECMT (Extracteur de Concepts Multi-Terminologique [Sakji et coll, 2010]) et l'OnBaSAM (Ontology-Based Semantic Annotation Module [Cardoso et coll, 2016]). Fondés sur deux technologies différentes, ils permettront de mettre au point un outil performant d'annotation sémantique. Ensuite, il faudra extraire les informations sur les patients et les maladies à partir des comptes rendus d'hospitalisation et d'autres textes présents dans le dossier patient. L'outil d'annotation sera complété par la mise à disposition d'outils statistiques adaptés aux études spécifiques de l'analyse des prescriptions hors AMM.

Les résultats de ce travail de recherche permettront aux psychiatres et aux pharmaciens d'obtenir les données nécessaires pour étudier les prescriptions hors AMM ainsi que leur nature, leur fréquence et leur motivation. Par le passé, les découvertes de nouvelles catégories ont été faites à l'occasion d'observations fortuites comme pour les antidépresseurs, ou antipsychotiques par exemple. Ce travail sera une opportunité de suivre la mise en pratique des recommandations et une source pour identifier de nouveaux usages. La base de connaissances des médicaments, incluant leurs indications et doses maximales, restera ensuite disponible pour une utilisation future.

5.4 Objectifs du stage

Les objectifs initiaux de mon stage étaient l'alignement de référentiels bibliographiques, l'utilisation du serveur HeTOP et la contribution à sa mise à jour. Ces objectifs de stage ont évolué au fur et à mesure des avancées sur ces différents travaux.

5.4.1 Objectif principal

Mon objectif principal a été de proposer un référencement à jour de la littérature scientifique médicale afin d'aider les professionnels de santé dans leur information et prise de décision lors de la prescription hors AMM de nombreux médicaments. Ainsi, j'ai participé à l'alignement de référentiels bibliographiques à la fois pour le projet ANR « PsyHAMM » mais également pour d'autres projets hors du domaine psychiatrique. J'ai été initié à l'utilisation du serveur HeTOP et plus particulièrement à son versant axé sur le médicament et qui se nomme « HeTOP médicament ».

HeTOP est un serveur basé sur une classification ontologique et terminologique. Il permet une représentation des connaissances et des interactions entre différentes classes dans le champ des données médicales d'après la sémantique développée autour des notions qui lui sont intégrées. La figure 1 ci-dessous illustre l'ensemble des notions autour de chaque médicament référencé sur HeTOP ; chacune de ces notions possède une sémantique permettant la classification de l'ensemble des médicaments.

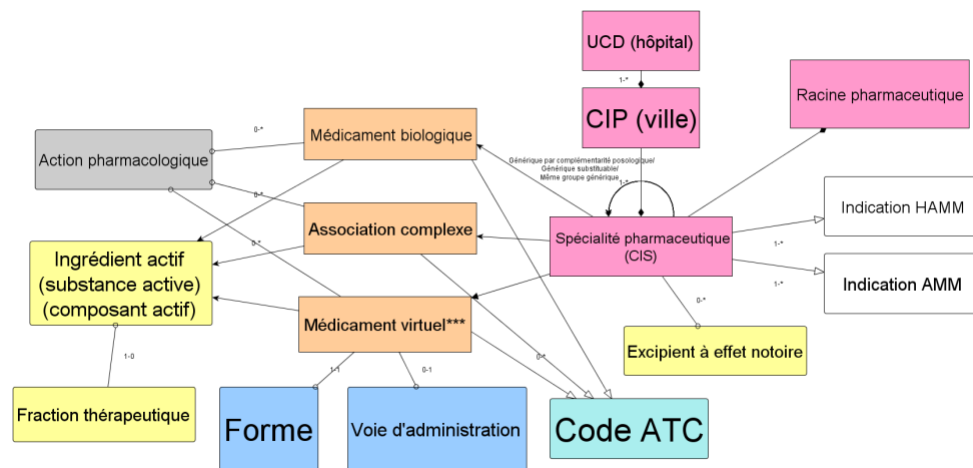


Figure 1: modèle sémantique du médicament en France

Dans le cadre de ce travail de référencement, j'ai été encadré par Catherine Letord, pharmacienne rattachée au Centre Hospitalo-Universitaire (CHU) de Rouen, membre du LIMICS et de l'Inserm U11 42 qui contribue au projet PsyHAMM. Elle m'a apporté l'ensemble des références bibliographiques utilisées au début de mon stage et j'ai ainsi traité un grand nombre de celles-ci afin de les intégrer à HeTOP. Par la suite, j'ai fait mes propres recherches afin de continuer les travaux qui avaient été démarrés avant mon arrivée dans le projet. Jean Charlet et Catherine Letord m'ont encadré au cours de ces recherches afin de valider leur contenu dans le cadre du projet PsyHAMM.

5.4.2 Objectifs secondaires

Au cours de mon travail sur HeTOP, le Professeur Darmoni rédigeait un article à son propos. Il m'a alors chargé de le relire. J'ai donc participé à la correction et l'ajout de certains éléments de l'article. Par la suite, le Professeur Darmoni a souhaité que je participe à la rédaction d'un article scientifique concernant HeTOP dans le cadre d'une évaluation qualitative du serveur. Jean Charlet, mon maître de stage, et le professeur Stefan Darmoni m'ont encadré au cours de la rédaction de cet article.

5.5 Réalisation des objectifs

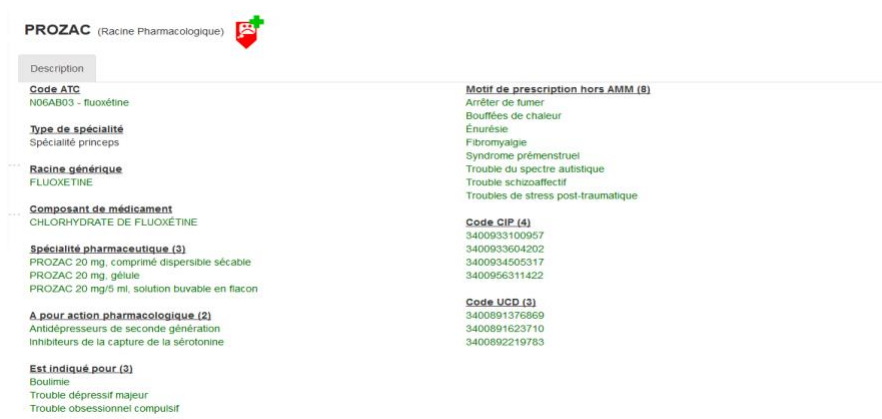
Les objectifs de ce stage m'ont permis d'aborder différents aspects des travaux du LIMICS pendant ces six mois.

En premier lieu, j'ai réalisé l'alignement de référentiels en maladies psychiatriques dans le cadre du projet PsyHAMM et également non psychiatriques pour des prescriptions hors AMM. J'ai pu renseigner au mieux le serveur HeTOP avec les références bibliographiques issues des travaux de Catherine Letord auxquels j'ai joint mes recherches. J'ai ainsi consulté de nombreux articles sur Pubmed se trouvant dans la liste des annexes de ce rapport. J'ai rendu compte de mes recherches à Catherine Letord et Jean Charlet par des tableaux Excel.

DCI	Nom de spécialité	Adulte/Enfant	Indication hors AMM	Références
Citalopram	Seropram	Adulte	Alzheimer	Antonsdottir IM, Smith J, Keltz M, Porsteinsson AP. Advancements in the treatment of agitation in Alzheimer's disease. Expert Opin Pharmacother. 2015;16(11):1649-56. doi: 10.1517/14656566.2015.1059422. Review. PubMed PMID: 26159445.

Tableau 1: exemple de ligne de tableau de compte-rendu des recherches hors AMM en psychiatrie

Ces recherches ont concerné les indications psychiatriques hors AMM du projet PsyHAMM, toujours sous la supervision de Catherine Letord. Au-delà de ces travaux de recherche, nous avons renseigné les indications hors AMM données par les équipes de médecins et pharmaciens de l'hôpital Saint-Anne qui sont partenaires de ce projet. J'ai ainsi travaillé afin d'identifier la littérature à la fois la plus pertinente et la plus récente pour renseigner « HeTOP médicament » (interface du serveur HeTOP consacrée spécifiquement aux informations sur les médicaments). J'ai fait part de mes différentes observations à l'équipe en charge de la base de données quand cela semblait nécessaire afin de contribuer à l'améliorer. C'est ainsi que j'ai pu renseigner la zone « Commentaires » de l'onglet « Indications hors AMM » des différents médicaments étudiés. La figure 2 ci-dessous présente une capture d'écran de « HeTOP médicament » lors de l'affichage d'une recherche de spécialité pharmaceutique.



PROZAC (Racine Pharmacologique)	
Description	
Code ATC N06AB03 - fluoxétine	Motif de prescription hors AMM (8) Arrêter de fumer Bouffées de chaleur Enurésie Fibromyalgie Syndrome prémenstruel Trouble du spectre autistique Trouble schizoaffectif Troubles de stress post-traumatique
Type de spécialité Spécialité princeps	
Racine générique FLUOXÉTINE	
Composant de médicament CHLORHYDRATE DE FLUOXÉTINE	
Spécialité pharmaceutique (3) PROZAC 20 mg, comprimé dispersible sécable PROZAC 20 mg, gélule PROZAC 20 mg/5 ml, solution buvable en flacon	Code CIP (4) 3400933100957 3400933604202 3400934505317 3400956311422
A pour action pharmacologique (2) Antidépresseurs de seconde génération Inhibiteurs de la capture de la sérotonine	Code UCD (3) 3400891376869 3400891623710 3400892219783
Est indiqué pour (3) Boulimie Trouble dépressif majeur Trouble obsessionnel compulsif	

Figure 2: exemple d'informations sur un médicament par « HeTOP médicament »

Lorsque l'on s'intéresse à cet exemple, on constate 8 indications hors AMM. En cliquant sur une indication, on obtient la liste des médicaments prescrits. HeTOP propose des informations complémentaires à cette recherche. La figure 3 ci-dessous donne une illustration

de la recherche de « Prozac » sur HeTOP. Dans l'onglet « Relations », on trouve les indications de l'AMM du Prozac et les indications hors AMM.

The screenshot shows the HeTOP web application. At the top, there's a search bar with 'prozac' entered. Below it, a sidebar on the left lists search results under 'Meilleurs candidats'. The main content area is titled 'PROZAC (Racine Pharmacologique)' and has tabs for 'Description', 'Hiérarchies', 'Relations' (selected), 'PubMed / Doc/CISMeF', and 'Curation'. Under the 'Relations' tab, there are buttons for 'Ajouter une métadonnée', 'Intra-terminologiques', and 'Inter-terminologiques'. The main content area displays a list of semantic types and their counts: Type(s) sémantique(s) (1), Métatérme(s) (5), Code(s) ATC (1), Spécialité(s) pharmaceutique(s) (3), A pour principe actif (2), A pour voie(s) d'administration (1), A pour action(s) pharmacologique(s) (2), Est indiqué pour (3), and Correspondances UMLS (même concept) (1).

Figure 3: exemple d'informations sur un médicament avec « HeTOP »

La figure 4 donne un aperçu de la fenêtre des « Motif(s) de prescription hors AMM ». On y retrouve différentes indications pour lesquelles on obtient des informations en cliquant. On aperçoit également un encadré portant une bulle bleue à côté de chaque ligne. Cet encadré est la section « Commentaires » et renvoie à une fenêtre dans laquelle sont renseignées les recherches que j'ai effectuées au cours de mon stage.

The screenshot shows the HeTOP web application with the 'Relations' tab selected. The main content area displays a list of indications for off-label use (Motif(s) de prescription hors AMM). The list includes: anorexie mentale/traitement médicamenteux, Arrêter de fumer, bouffées de chaleur/traitement médicamenteux, cataplexie/traitement médicamenteux, énurésie/traitement médicamenteux, fibromyalgie/traitement médicamenteux, syndrome prémenstruel/traitement médicamenteux, Trouble du spectre autistique/traitement médicamenteux, Trouble schizoaffectif/traitement médicamenteux, and troubles de stress post-traumatique/traitement médicamenteux. Each entry has a 'Descripteur MeSH/Qualificatif MeSH' and a blue bubble icon. Below the list, there are sections for 'Alignements manuels CISMeF (2)' and 'Alignements automatiques exacts (par équipe CISMeF) (1)'.

Figure 4: exemple qui montre les motif(s) de prescription hors AMM du Prozac

La figure 5 montre les informations présentes dans l'onglet « Commentaires ». Cet onglet a été adapté au cours de mon stage afin de pouvoir contenir le maximum de documentation à propos des indications hors AMM pour les différents médicaments.

Après recueil des réponses en quantité suffisante, nous analyserons de manière statistique les notes obtenues (moyenne, écart-type, test du Khi-deux) et les verbatims. Nous mettrons en évidence la corrélation de certains paramètres et dégagerons les premières conclusions concernant l'usage d'HeTOP par les évaluateurs. Ci-dessous, le tableau donne un exemple de recueil de résultats de l'évaluation qualitative. En obtenant des cohortes suffisamment élevées, nous aurons assez de puissance pour effectuer nos tests statistiques.

N° participant	Intérêt sur les compétences	Intérêt pédagogique	Simplicité d'affichage	Sous-groupe
1	8.4	8.9	7.7	5A I&R
2	8.8	10	6.1	5A Officine

Tableau 2: exemple de recueil des résultats de l'évaluation d'HeTOP

Voici une présentation des premiers résultats obtenus avec la cohorte du groupe d'étudiants en pharmacie pour n=20.

	Intérêt sur les compétences	Intérêt pédagogique	Simplicité d'affichage	Sous-groupe
5A I&R	X = 7.68 ± 0.97 (σ)	X = 8.38 ± 0.75 (σ)	X = 7.44 ± 1.44 (σ)	10
5A Officine	X = 7.95 ± 1.55(σ)	X = 8.75 ± 1.30 (σ)	X = 7.53 ± 1.64 (σ)	4
5A Internat	X = 7.33 ± 0.95 (σ)	X = 6.77 ± 1.05 (σ)	X = 5.78 ± 1.59 (σ)	6

Tableau 3: résultats de l'évaluation qualitative pour une cohorte de n=20 participants

Nous sommes actuellement en cours de rédaction de l'article scientifique en anglais où le professeur Darmoni et Jean Charlet m'apportent leur encadrement précieux. Cet exercice nouveau me permet de me confronter à l'exigence du monde scientifique et est un moyen d'exposer et mettre en valeur le travail que j'ai réalisé au cours de ce stage au LIMICS. Au moment de l'écriture de ce rapport, nous sommes toujours en cours de recueil des résultats et en rédaction de l'article.

Enfin, dans un dernier temps, Jean Charlet m'a formé à la discipline de l'ontologie sur le logiciel Protégé. C'est au cours d'une journée de formation qu'il a donnée au laboratoire que j'ai pu bénéficier des enseignements qu'il dispense habituellement à l'université. J'ai appris à créer une ontologie, l'enrichir, la modifier et obtenir des résultats à partir de celle-ci. Suite à cette formation, j'ai manipulé l'ontologie réalisée par Sonia Cardoso et Jean Charlet dans le cadre de leurs travaux sur la sclérose latérale amyotrophique. J'ai participé à l'alignement des classes et des concepts ainsi que la traduction de certains concepts lors de l'enrichissement de l'ontologie.

5.6 Conclusion

Sur le plan professionnel, ce stage m'a permis d'intégrer le monde de la recherche dans un organisme public. Je me suis imprégné de l'ambiance du laboratoire au cours de ces 6 mois et on m'y a transmis l'importance d'avoir une vision critique. Le LIMICS mène et collabore sur de nombreux projets. J'ai ainsi bénéficié d'une ouverture sur les avancées techniques dans le domaine médical, en particulier sur les projets liants médical et ingénierie. L'essentiel de mon travail aura été associé de façon directe ou indirecte au serveur HeTOP, projet du LIMICS. J'ai pu réaliser à quel point cet outil est bien documenté et tend à représenter de façon optimale les connaissances dans le domaine du médical qui est en constante avancée. En représentant les connaissances et en cherchant à être le plus à jour possible sur la littérature médicale, HeTOP est un outil potentiel pour dégager les médicaments d'intérêt dans le cadre des prescriptions hors AMM. Il pourrait potentiellement permettre de faire réviser leur situation, et impacter alors le coût de la prise en charge du patient dans un but d'amélioration de l'efficacité du système de santé français. J'ai suivi avec beaucoup d'intérêt la formation sur l'ontologie dispensée par mon maître de stage Jean Charlet. Ce fut une opportunité d'être initié à une méthode d'intérêt dans le domaine des connaissances en santé.

Sur le plan personnel, ce stage m'a permis de découvrir de façon plus concrète le monde de la recherche dans le domaine médical. J'ai été sensibilisé aux nombreuses opportunités qu'il contient, à l'aspect pluridisciplinaire du paysage de la recherche médicale en France. J'y ai beaucoup apprécié l'ambiance de travail en grande autonomie, la confiance au sein de l'équipe et la convivialité. J'ai travaillé sur les différents objectifs de mon stage et je les ai atteints grâce à une équipe à l'écoute et dont j'ai appris tant sur le plan technique qu'humain. Mes encadrants, les chercheurs du laboratoire et mes collègues ont été des rencontres enrichissantes dans le cadre de mon développement personnel.

En conclusion, ma participation au projet ANR « PsyHAMM » fut enrichissante à tous les niveaux. Ayant été sensibilisé au contexte de la psychiatrie en France, j'ai pris du recul pour comprendre les enjeux de ce projet. L'importance des dépenses de santé en France dans le domaine de la psychiatrie et le nombre de prescriptions hors AMM ainsi que leur prise en charge par la Sécurité Sociale sont des éléments qui donnent à penser qu'HeTOP possède un rôle important à jouer.

Ce stage constitue également une bonne entrée en matière pour le master 2 de pharmaco-épidémiologie auquel je suis inscrit à Sorbonne Université pour la rentrée 2019. En effet, je vais être formé à l'évaluation d'indicateurs autour du médicament en vie réelle dans une perspective d'évaluation de l'efficacité du système de santé en France. Ce master 2 me formera à devenir acteur, je l'espère, autour de ces enjeux lors de ma carrière professionnelle.

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Un modèle sémantique d'identification du médicament en France

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Résumé : il n'existe pas de standard universellement accepté pour nommer les médicaments. L'identification du médicament a fait l'objet de nombreux travaux de normalisation. Notre objectif est de définir un modèle formel du médicament en français pour lier les différentes entités manipulables autour du médicament. Ce modèle formel vise un double sous-objectif : (a) créer et instancier une ontologie formelle du médicament ; (b) créer une terminologie du médicament, intégrable dans un serveur de terminologies. À terme, ces ressources seront des outils puissants pour, notamment, supporter la recherche d'information dans des bases de médicaments ou des entrepôts de données. Ils seront mis librement à disposition de la communauté.

Mots-clés : ontologie ; terminologie ; serveur de terminologie ; modèle formel ; médicament.

1 Introduction

Bien que le médicament soit fini, identifiable, il n'existe pas de standard universellement accepté pour le représenter (Cimino 1999). Selon le point de vue auquel on se place, on peut le définir à un niveau moléculaire (comme une substance active), à un niveau clinique (comme un produit capable de traiter une pathologie) ou encore à un niveau physique (comme une présentation destinée à satisfaire la prescription et délivrable au patient). L'identification du médicament peut donc se concevoir à divers niveaux ayant des degrés d'abstraction plus ou moins grands (Sperzel 1998) (i) une présentation, un produit manufacturé ou un ingrédient correspondent à des objets physiques, (ii) un produit clinique ou une fraction thérapeutique sont de pures abstractions.

L'identification du médicament a fait l'objet de nombreux travaux de normalisation dont les plus récents définissent l'identification du produit médicinal et du produit pharmaceutique (ISO 11615, ISO 11616, ISO 20443, ISO 11238, ISO 11239, ISO 11240) afin de rendre le partage international de l'information sur le médicament possible. Le référentiel résultant sera disponible en 2020 au niveau de l'agence européenne du médicament (EMA). D'autres modèles ont été adoptés pour représenter le médicament dans les bases de données sur le médicament (Broverman 1998, DMD¹), ou pour servir de pivot entre des bases des données sur le médicament (RxNorm²). Dans ces modèles, se retrouve cette dualité entre virtuel et réalité et les relations de composition entre ingrédients actifs, dosages et formes.

¹ <https://apps.nhs.uk/nhs.uk/DMDBrowser/DMDBrowser.do>

² <https://www.nlm.nih.gov/research/umls/rxnorm>

7 Liste des annexes et annexes

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