U 33/2013 rd

Statsrådets skrivelse till riksdagen om att Finland ansluter sig till det europeiska konsortiet för translationell medicinsk forskningsinfrastruktur (anslutande till konsortiet EATRIS ERIC).

I enlighet med 96 § 2 mom. i grundlagen översänds till riksdagen en promemoria om att Finland ansluter sig till det europeiska konsortiet för translationell medicinsk forskningsinfrastruktur EATRIS ERIC jämte handlingar gällande detta konsortium.

Helsingfors den 6 juni 2013

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UNDERVISNINGS- OCH KULTURMINISTERIET **PROMEMORIA**

FÖRSLAG TILL FINLANDS ANSLUTNING TILL DET EUROPEISKA TRANSLATIONELLA MEDICINSKA FORSKNINGSINFRASTRUKTURKONSORTIET EATRIS ERIC

1 Bakgrund

1.1 Det europeiska forskningsområdet och forskningens infrastrukturer

Det europeiska forskningsområdet (ERA) är ett begrepp som infördes i början av 2000-talet i kommissionens meddelande Mot ett europeiskt område för forskningsverksamhet (KOM(2000)6). Begreppet har etablerats snabbt som definition på den europeiska forsknings- och innovationspolitikens mål och verksamhetssätt. ERA har inkluderats i artikel 179.1 i Fördraget om Europeiska unionens funktionssätt (FEUF) där det beskrivs på följande sätt: ”Unionen ska ha som mål att stärka unionens vetenskapliga och tekniska grund genom att åstadkomma ett europeiskt forskningsområde med fri rörlighet för forskare, vetenskapliga rön och teknik, att främja utvecklingen av unionens konkurrensförmåga, inbegripet inom unionens industri, och att underlätta alla forskningsinsatser som anses nödvändiga enligt andra kapitel i fördragen.” Det europeiska forskningsområdet har en stark anknytning till Europa 2020-strategin och flaggskeppsprojektet ”Innovationsunionen” som hör till den.

Samarbete på området för forskningsinfrastrukturer har blivit nödvändigt eftersom stora och dyra forskningsanläggningar kan byggas och användas endast genom samarbete mellan flera länder, och å andra sidan erbjuder datatekniken alldeles nya möjligheter att förena omfattande material eller mätningsresultat samt distansanvändning av infrastrukturer som finns någon annanstans. För att bedöma forskningsinfrastrukturbehovet på Europanivå och för att bereda en vägkarta grundade EU-länderna och kommissionen tillsammans Europeiska strategiska forumet för forskningsinfrastrukturer (ESFRI) vars medlemmar representerar forskningsförvaltningen i EU:s medlemsländer och länder som anslutit sig till EU:s ramprogram för forskning. På rådets uppmaning publicerade ESFRI den första planen för forskningsinfrastrukturer, den så kallade vägkartan, år 2006. Vägkartan har uppdaterats 2008 och 2010. Till vägkartan har man valt 50 gemensamma europeiska forskningsinfrastrukturprojekt.

Med EU:s ramprogram för forskning har man stött planeringen av nya forskningsinfrastrukturer samt utvidgning av användningen av existerande infrastrukturer och intensifierat samarbete. En motsvarande stödform ingår i det kommande EU-programmet för forskning och innovation Horisont 2020.

1.2 ERIC-förordningen som juridisk referensram för forskningsinfrastrukturerna

Tidigare har de huvudsakliga juridiska verksamhetsformerna som använts för infrastrukturer som är gemensamma för flera länder varit en internationell organisation som grundar sig på ett mellanstatligt avtal eller ett företag eller en stiftelse som bygger på lagstiftningen i det land där infrastrukturen finns. Att grunda och driva en internationell organisation är mödosamt och att använda lagstiftningen i ett land som grund för en organisation som är gemensam för flera länder kan medföra problem på grund av skillnader i nationella lagstiftningar.

För att skapa gemensamma verksamhetsprinciper, för att göra de administrativa strukturerna lättare och för att ordna ställningen som juridisk person lämnade kommissionen med stöd av artikel 171 FEU (nuvarande artikel 187 FEUF) ett förslag till rådets förordning om ett konsortium för europeisk forskningsinfrastruktur (ERIC) sommaren 2008. Statsrådet lämnade U-skrivelsen U 54/2008 rd om förordningsförslaget till riksdagen i oktober 2008. Rådet godkände förordningen sommaren 2009 (EG/723/2009)

och den trädde i kraft 28.8.2009. I förordningen definieras ERIC:s juridiska status, villkor och förfaranden som gäller grundandet, krav gällande infrastrukturen och användningen av den, stadgarnas huvudsakliga innehåll inklusive medlemmarnas rättigheter och skyldigheter, förvaltningsstrukturen, budgetprinciperna, principer gällande räkenskaper och revision, tillämplig lag och upplösningsförfaranden. Vidare ingår i stadgarna bestämmelser om datastrategi, immaterialrättigheter, anställning och principer för upphandling.

I förordningen ges kommissionen fullmakt att besluta på basis av ansökan från medlemsländerna som deltar i forskningsinfrastrukturen om infrastrukturen kan beviljas status som europeiskt forskningsinfrastrukturkonsortium. Kommissionen utvärderar ansökan, vid behov med hjälp av oberoende experter, och fattar beslut om att grunda en forskningsinfrastruktur eller avslår ansökan om den anser att villkoren enligt förordningen inte uppfylls. Kommissionen biträds av en rådgivande kommitté i enlighet med komitologiförfarandet.

Med stöd av bestämmelsen i förordningen får ett ERIC juridisk personlighet från den dag kommissionens beslut om grundande träder i kraft. Ett ERIC beviljas omfattande rättshandlingsförmåga. Det räknas inte som ett EU-organ, men erkänns efter värdstatens meddelande som ett sådant internationellt organ eller en organisation som med stöd av mervärdesskattedirektivet (2006/112/EG) och punktskattedirektivet (92/12/EEG) under vissa bestämda förutsättningar är befriad från mervärdesskatt och punktskatt. I förordningen om verkställande av mervärdesskattedirektivet (EU/282/2011) har man därtill bestämt villkoren som ett ERIC måste uppfylla för att mervärdesskattefriheten kan tillämpas. Ett ERIC:s upphandlingsförfaranden hör inte till tillämpningsområdet för direktivet om offentliga upphandlingar (2004/18/EG).

På ERIC tillämpas i första hand EU-lagstiftningen och i andra hand lagstiftningen för hemstaten samt, om verksamhetsställen finns i flera stater, lagstiftningen för staten där ifrågavarande verksamhetsställe finns i frågor som gäller bl.a. hälsa, miljöskydd, hantering av farliga ämnen samt beviljande av koncessioner. Ett ERIC:s hemplats ska ligga på territoriet för ett EU-medlemsland eller för ett land som anslutit sig till gemenskapens ramprogram för forskning.

1.3 Forskningsinfrastrukturpolitiken i Finland

I samband med det europeiska utvecklingsarbetet kartlade Finland sina egna nationella forskningsinfrastrukturer samt utarbetade en vägkarta om viktiga nya forskningsinfrastrukturer. Den nationella vägkartan publicerades i början av 2009 (Kansallisen tason tutkimusinfrastruktuurit, nykytila ja tiekartta; Undervisningsministeriets publikationer 2009:1). Till vägkartan godkändes 20 nya forskningsinfrastrukturer varav 13 även ingick i ESFRI:s europeiska vägkarta.

För att utveckla den nationella forskningsinfrastrukturpolitiken och finansiera kostnaderna med anknytning till forskningsinfrastrukturer har statsbudgeten (under undervisnings- och kulturministeriets förvaltningsområde) sedan 2012 haft ett forskningsinfrastrukturmoment (29.40.22). Den 2 december 2011 gav undervisnings- och kulturministeriet Finlands Akademi till uppgift att tillsätta en expertgrupp för de nationella forskningsinfrastrukturerna samt att förvalta ovannämnda anslag (29.40.22). Finlands Akademi tillsatte en expertgrupp för forskningsinfrastrukturer, den s.k. FIRI-sakkuniggruppen, den 12 april 2012. Till expertgruppens uppgifter hör därtill att uppdatera vägkartan för forskningsinfrastrukturer och att utarbeta förslag för utveckling av den nationella forskningsinfrastrukturpolitiken. Gruppens uppgift är också att ge det behöriga ministeriet rekommendationer om Finland ska ansluta sig till en europeisk eller någon annan internationell forskningsinfrastruktur och i vilken omfattning kostnader för anslutningen kan betalas ur forskningsinfrastrukturmomentet.

FIRI-sakkuniggruppen har den 22 april 2013 rekommenderat att Finland ansluter sig till EATRIS ERIC och rekommenderat att Finlands Akademi bereder sig på att finansiera kostnaderna som Finlands medlemskap i projektet föranleder ur forskningsinfrastrukturmomentet (29.40.22) i enlighet med sin finansieringsandel. EATRIS är den första

forskningsinfrastrukturen enligt den nya ERIC-bestämmelsen som Finland har som avsikt att ansluta sig till.

2 Huvudsakligt innehåll

Finland har som avsikt att som grundande medlem ansluta sig till det europeiska forskningsinfrastrukturkonsortiet EATRIS ERIC, vars värdland är Nederländerna. I första skedet förbinder sig Finland att vara medlem i fem år. Avsikten är att utnämna Helsingfors universitets institut för molekylärmedicin (Institute for Molecular Medicine Finland, FIMM) till Finlands nationella samordnande enhet. FIMM samordnar den nationella EATRIS ERIC-verksamheten i vilken Östra Finlands universitet, Tammerfors universitet, Åbo universitet samt Teknologiska forskningscentralen VTT medverkar. Med hjälp av denna helhet ansvarar man för byggandet av den nationella EATRIS-infrastrukturen och produktionen av tjänster som medlemskapet förutsätter.

Finland har för avsikt att i enlighet med stadgarna utnämna högst 2 personer som använder nationell bestämmanderätt i EATRIS ERIC-konsortiets stadgeenliga medlemsförsamling, som är det högsta beslutande organet. Medlemsförsamlingen beslutar om EATRIS-forskningsinfrastrukturens verksamhet, finansiering och medlemsavgiftens belopp, samt vid behov om upplösning av infrastrukturen. Medlemsförsamlingen beslutar också om val och avskedande av forskningsdirektören och generaldirektören samt de högsta tjänstemännen.

Kostnaderna för deltagandet består av medlemsavgiften enligt stadgarna, upprätthållandet av den nationella forskningsinfrastrukturen och produktionen av infrastrukturtjänster för EATRIS ERIC.

Anslutning som grundande medlem förutsätter att Finland till värdlandet sänder en undertecknad förbindelse att delta i EATRIS ERIC som grundande medlem. Förbindelsen ges i enlighet med stadgarna för de följande fem åren.

Den 15 februari 2013 har undervisnings-, kultur- och forskningsministeriet i Nederländerna i enlighet med ERIC-förordningen sänt europeiska kommissionen en EATRIS ERIC-ansökan, i vilken förutom Nederländerna även Italien, Danmark och Tjeckien bekräftat att de ansluter sig som medlemmar och Frankrike som observatör. Länder som vill bli grundande medlemmar kan ansluta sig till EATRIS ERIC även efter att ansökan inlämnats, men innan kommissionen fattat beslut om saken. I beredningen av EATRIS ERIC har totalt nio länder deltagit: Danmark, Finland, Frankrike, Italien, Nederländerna, Norge, Spanien, Tjeckien och Tyskland. Därtill har Estland, Portugal, Slovenien och Turkiet anmält sitt intresse som nya kandidater.

Kommissionen har för avsikt att fatta beslutet om grundandet av EATRIS ERIC i juni 2013. EATRIS ERIC får juridisk personlighet när kommissionen fattat sitt beslut. Beslutet publiceras i unionens officiella tidning. Därefter kan nya medlemmar tas till EATRIS ERIC enligt förfarandet i stadgarna.

2.1 EATRIS ERIC:s uppgift

EATRIS ERIC-konsortiets uppgift är att bygga, upprätthålla och utveckla ett forskningsinfrastrukturnätverk för europeisk translationell medicin på hög nivå genom att samla ländernas ledande forskningsenheter, deras forskningsinfrastrukturkapacitet och specialkompetens för europeiska och andra universitets, forskningsinstitutioners och företags forskares och forskarsammanslutningars användning.

Det främsta målet är att erbjuda en forskningsinfrastrukturhelhet på toppnivå som effektiviserar utvecklingen av den medicinska och biologiska basforskningens resultat och uppfinningar till viktiga nya tillämpningar inom hälso- och sjukvården, bl.a. diagnostiska metoder, läkemedel och andra vårdformer. Utöver forskningsapparatur och material erbjuder EATRIS ERIC bl.a. samordning och kvalitetskontroll av gemensamma verksamhetsprocesser, stöd för lösning av frågor som beror på skillnader i medlemsländernas lagstiftningar. Därtill samordnar konsortiet forskarnas tillgång till de bästa prestationsorterna med tanke på forskningen. Det erbjuder även ett forum för samarbete mellan forskare, läkare och industrin för att utnyttja forskningsresultat och producera innovationer.

Forskningsinfrastrukturen består av fem delhelheter vilka är
— biomarkörer
— mikromolekyler
— radioaktiva spårämnen och bilddiagnostik
— vacciner och
— cell- och genterapier.

Finland har en betydande roll i EATRIS-forskningsinfrastrukturen. På basis av beredningen ansvarar Finland för en av forskningsinfrastrukturens fem delhelheter, biomarkörer. Biomarkörer är biologiska spårämnen med hjälp av vilka man kan bl.a. bedöma risken för insjuknande, diagnostisera sjukdomar noggrannare samt prognostisera vårdresponsen. Biomarkörer bidrar till utvecklingen av bättre vårdformer och de är också en förutsättning för tillämpningar inom personlig medicin. Vid EATRIS utvecklas och valideras biomarkörer bl.a. med hjälp av material i biobanker.

Finlands nationella samordningsenhet och det nationella nätverket som det samordnar erbjuder via EATRIS tjänster till såväl nationella forskare som forskare från andra länder. På motsvarande sätt har forskare vid finländska universitet, forskningsinstitutioner och företag möjlighet att använda EATRIS-infrastrukturens alla europeiska tjänster i sin egen forskning på de villkor som finns i stadgarna.

EATRIS ERIC:s verksamhet är inte vinstdrivande. Begränsad affärsverksamhet är dock möjlig med stöd av ERIC-förordningen och stadgarna.

2.2 EATRIS ERIC:s medlemmar, rättigheter och skyldigheter

2.2.1 Medlemmar

Europeiska unionens medlemsländer, stater utanför EU och mellanstatliga organisationer kan bli medlemmar i konsortiet. EU:s medlemsstater ska ha röstmajoritet i ERIC:s medlemsförsamling. Enligt stadgarna beslutar medlemsförsamlingen om godkännandet av nya medlemmar. Konsortiet kan även ha observatörsmedlemmar.

2.2.2 Rättigheter

Medlemmarna har rätt att utnämna sina företrädare och att delta i verksamheten för EATRIS ERIC:s högsta beslutande organ, dvs. medlemsförsamlingen, och att använda sin rösträtt (1 röst per medlem), att besluta om riktlinjer på politiknivå för konsortiets verksamhet, verksamhetsstrategier, budgeten, fastställandet av verksamhetsberättelsen och bokslutet samt om val och avskedande av ledande personal. Medlemslandets forskningssammanslutning har rätt att delta i EATRIS ERIC:s forskningsinfrastrukturtjänster och andra tillställningar.

Observatörsmedlemmar antas för en viss tid om tre år. De har rätt att delta i medlemsförsamlingen, men har ingen rösträtt.

2.2.3 Skyldigheter

Enligt stadgarna ska en medlem utnämna en nationell samordnande enhet och en direktör för den som deltar i ordnandet och utvecklandet av EATRIS ERIC:s verksamhet i de nationella direktörernas församling. Medlemmen ska betala medlemsavgiften som bestäms av medlemsförsamlingen årligen, upprätthålla och utveckla den nationella forskningsinfrastrukturen och producera tjänster i enlighet med sina plikter samt tekniska arrangemang som möjliggör tillgång till tjänsterna för forskare som kommer från det egna landet och via EATRIS ERIC samt sörja för uppföljningen.

Observatörsmedlemmar betalar 25 % av en ordinarie medlems medlemsavgift.

2.3 EATRIS ERIC:s förvaltning och beslutsprocess

Enligt stadgarna används den högsta beslutande makten i EATRIS ERIC av medlemsförsamlingen. Generaldirektören företräder EATRIS ERIC och undertecknar avtal för konsortiets del.

För forskningsinfrastrukturens vetenskapliga innehåll och utvecklingen av det svarar forskningsdirektören i samarbete med de nationella direktörerna och generaldirektören.

EATRIS ERIC:s samordnings- och stödenhet, där infrastrukturberedningen och verkställandet leds av generaldirektören tillsammans med forskningsdirektören och med hjälp av ett sekretariat, ligger i Amsterdam i Nederländerna. Samordnings- och stödenheten har redan grundats med stöd av det tillfälliga förvaltningsavtalet. Denna enhet jämte direktörerna fortsätter sitt arbete fram till det att EATRIS ERIC grundats och medlemsförsamlingen beslutar om enhetens arbetes fortsättning.

2.4 Finansieringen av EATRIS ERIC

Åren 2014—2017 kommer EATRIS ERIC:s medlemsavgift att vara minst 50 000 och högst 140 000 euro beroende på antalet medlemsländer. Värdlandet Nederländerna har beslutat att stödja beredningen av EATRIS ERIC med 500 000 euro per år åren 2011—2015. Länderna som deltar på basis av det tillfälliga förvaltningsavtalet har betalat som finansieringsandel i samband med beredningen 125 000 euro åren 2011—2012 och 116 000 euro år 2013. Finlands finansieringsandelar har betalats av Helsingfors universitet.

2.5 Finlands deltagande i EATRIS ERIC

Finland har deltagit i den vetenskapliga beredningen av EATRIS ERIC år 2008 och i den administrativa beredningen sedan 2009. Undervisnings- och kulturministeriet har undertecknat ett samförståndsprotokoll som gäller beredningen den 6 september 2010 samt det tillfälliga förvaltningsavtalet för att fortsätta beredningen den 10 mars 2011. Den 26 november 2012 förlängdes det tillfälliga förvaltningsavtalet fram till det att EATRIS ERIC grundas eller högst till utgången av 2013.

För att nå synergier och ett bredare kompetenskluster har Finlands deltagande i EATRIS ERIC beretts som ett konsortium i vilket ingår BBMRI-infrastrukturen för biobankmaterial och ELIXIR-forskningsinfrastrukturen för bioinformatiktjänster. Undervisnings- och kulturministeriet, social- och hälsovårdsministeriet och arbets- och näringsministeriet har kommit överens om denna beredning år 2010. I konsortiet medverkar Helsingfors universitets institut för molekylärmedicin FIMM (EATRIS), Institutet för hälsa och välfärd THL (BBMRI) och IT-centret för vetenskap CSC (ELIXIR). Byggandet av konsortiets verksamhet har åren 2010-2012 understötts ur Finlands Akademis forskningsanslag, moment 29.40.51, riktad finansiering av forskningsinfrastrukturer. I beredningen på europeisk nivå har ovannämnda infrastrukturer beretts separat, vilket även återspeglas i tidtabellerna för den nationella behandlingen. Finlands synergiska modell har ansetts vara bra och även på europeisk nivå intensifierar man samarbetet i beredningen.

3 Förslagets rättsgrund och beslut om Finlands medverkan

EATRIS ERIC grundas med stöd av rådets förordning (nr 723/2009) om gemenskapens rättsliga ram för ett konsortium för europeisk forskningsinfrastruktur (Eric-konsortium), den s.k. ERIC-förordningen. Förordningen har antagits med stöd av artikel 171 FEU (numera artikel 187 FEUF). ERIC-förordningen och forskningsinfrastrukturerna som grundas med stöd av den stödjer målet i artikel 179.1 FEUF att skapa och stärka det Europeiska forskningsområdet, ERA.

ERIC grundas på basis av förordningen genom ett förfarande där kommissionen, efter att ha undersökt om medlemsländernas gemensamt presenterade ansökan och stadgar uppfyller villkoren i förordningen, fattar beslut om att grunda ERIC eller avslår ansökan. Enligt 93 § 2 mom. i grundlagen svarar statsrådet för den nationella beredningen av beslut som fattas i Europeiska unionen och beslutar om Finlands åtgärder som hänför sig till dem, om inte beslutet kräver godkännande av riksdagen. Riksdagens grundlagsutskott har ansett att 93 § 2 mom. även omfattar ärenden som inte formellt hör till unionens befogenheter, men som till innehållet och konsekvenserna motsvarar unionsärenden (GrUB 10/1998 rd s.27/1). Statsrådets allmänna sammanträde behandlar och avgör ärenden som avgörs av EU som nämns i nämnda lagrum samt ärenden som till innehållet och konsekvenserna motsvarar dem

om de förutsätter beslut av statsrådet. Enligt GL 96 § ska statsrådet sedan det fått kännedom om ett förslag till sådana rättsakter, fördrag eller andra åtgärder om vilka beslut fattas inom Europeiska unionen och som annars enligt grundlagen skulle falla inom riksdagens behörighet utan dröjsmål sända förslaget till talmannen. På basis av ovanstående begär undervisnings- och kulturministeriet av statsrådet fullmakt att för Finlands del underteckna ansökan om grundande av EATRIS-forskningsinfrastrukturkonsortiet som ska presenteras för kommissionen. Riksdagen deltar i beredningen enligt GL 96 §.

4 Förslagets konsekvenser

4.1 Vetenskapliga konsekvenser

EATRIS ERIC erbjuder en forskningsinfrastruktur på toppnivå som effektiviserar utvecklingen av den medicinska och biologiska basforskningens resultat och uppfinningar till viktiga nya tillämpningar inom hälso- och sjukvården, bl.a. diagnostiska metoder, läkemedel och andra vårdformer. EATRIS ERIC erbjuder utöver forskningsapparatur och material även samordning och kvalitetskontroll för gemensamma verksamhetsprocesser som sker i olika länder, ger stöd för lösning av frågor som beror på skillnader i medlemsländernas lagstiftningar under forskningens tid samt samordnar forskarnas tillgång till de bästa prestationsorterna med tanke på forskningen. Konsortiet erbjuder även ett forum för samarbete mellan forskare, läkare och industrin för att utnyttja forskningsresultat och producera innovationer.

Translationell forskning är ett forskningsområde som växer särskilt snabbt i Europa och Förenta Staterna. EATRIS ERIC ökar det samordnade samarbetet på europeisk nivå och stärker den finländska translationella forskningens utveckling, vetenskapliga kvalitet och utnyttjande av nya biomedicinska fynd. Ett omfattande nätverk är speciellt viktigt i fråga om forskning i sällsynta sjukdomar, där materialet i ett land är för begränsat för att nå slutsatser. Samarbetet tjänar även Finlands internationella exponering och genomslagskraft.

Finland har en betydande roll i EATRIS ERIC som ansvarande part för ett (1/5) av dess delområden, biomarkörer. Finland har därtill specialkompetens på området för cell- och genterapier samt delområdet radioaktiva spårämnen och bilddiagnostik. I Finland har EATRIS ERIC utvecklats som en del av ett konsortium i vilket ingår forskningsinfrastrukturen för biobanker BBMRI och forskningsinfrastrukturen för bioinformatik ELIXIR som bereds för närvarande. BBMRI är en europeisk biobankforskningsinfrastruktur där Finland har för avsikt att medverka bl.a. med befolkningsbaserade register och infrastrukturen skulle kompletteras med kliniskt material. ELIXIR är en europeisk forskningsinfrastruktur som producerar bioinformatiktjänster (förvaring, redigering, analysering, distribution, lagring av material) för den biomedicinska forskningen. Genom denna helhet har man ansett Finland ha unika möjligheter att utveckla bl.a. personlig medicin för hälso- och sjukvårdens och patienternas användning samt att ta fram nya produkter. Eftersom dessa forskningsinfrastrukturer behandlas separat på europeisk nivå och tidtabellerna för deras färdigställande avviker från varandra är det ändamålsenligt att fatta besluten om att ansluta sig till dem separat.

4.2 Ekonomiska konsekvenser

Enligt stadgarna ska Finland

1) betala en medlemsavgift på 50 000—140 000 euro per år, beroende på antalet medlemmar, enligt en förbindelse på fem år.

2) stödja byggandet och upprätthållandet av en nationell forskningsinfrastruktur (investeringar, tjänster och underhåll) samt producera forskningsinfrastrukturtjänster för EATRIS ERIC och nationella forskare

3) ordna en teknisk tjänst som möjliggör användning av forskningsinfrastrukturen för nationella forskare och forskare som kommer via EATRIS ERIC.

Värdlandet Nederländerna stödjer infrastrukturen med 500 000 euro per år fram till år 2015, varefter värdlandets stöd utvärderas på nytt. Värdlandet betalar också den normala medlemsavgiften.

Punkterna 1)—3) medför årliga kostnader på i genomsnitt ca 480 000 euro, varav man enligt rekommendationerna från expertarbetsgruppen för forskningsinfrastrukturer avser att täcka ca 380 000 euro ur forskningsinfrastrukturmomentet 29.40.22 i statsbudgeten. Den nationella värdorganisationen ska tillsammans med andra nationella samarbetspartners delta i kostnaderna på det sätt de sinsemellan kommer överens om.

Därtill ska Finland utnämna en representant till EATRIS ERIC:s högsta beslutande organ, dvs. medlemsförsamlingen.

5 Nationell beredning

Finland har deltagit i den vetenskapliga beredningen av EATRIS ERIC år 2008 och i den administrativa beredningen sedan 2009. Undervisnings- och kulturministeriet har undertecknat ett samförståndsprotokoll som gäller beredningen den 6 september 2010 samt det tillfälliga förvaltningsavtalet för att fortsätta beredningen den 10 mars 2011. Den 26 november 2012 förlängdes det tillfälliga förvaltningsavtalet fram till det att EATRIS ERIC grundas eller högst till utgången av 2013.

Finlands deltagande i forskningsinfrastrukturkonsortierna som avses i ERIC-förordningen har beretts sedan förordningen trädde i kraft, från år 2009. Undervisnings- och kulturministeriet har sammankallat en inofficiell arbetsgrupp i vars arbete justitieministeriet, utrikesministeriet och finansministeriet deltagit. Under beredningens gång har undervisnings- och kulturministeriet även begärt utlåtanden av justitie- och finansministerierna om det nationella tillämpandet och verkställandet av ERIC-förordningen (OPM 20/302/2009). Därtill har finansministeriet gett utrikesministeriet ett utlåtande (VM/62/00.00.05/2013) om vilken myndighet i Finland som är behörig att ge värdlandets meddelande om skattefrihet enligt ERIC-förordningen.

I beredningen har man i synnerhet strävat efter att utreda det mest ändamålsenliga sättet att tillämpa och verkställa ERIC-förordningen och att ordna Finlands deltagande i ERIC-projekten. Förordningen förutsätter att medlemsstaterna undertecknar ansökan om grundande av ett ERIC och den därtill hörande stadgan för ERIC som sänds till kommissionen. Kommissionen undersöker om medlemsländernas ansökan och stadga uppfyller villkoren i förordningen och kan sedan besluta om att grunda ett ERIC eller avslå ansökan. Betraktad som helhet bygger ansökan om grundande av ett ERIC och beslutet om detta på en förordning som är direkt tillämplig i medlemsstaterna. Därmed bör man anse att ställningstagandet om Finlands deltagande är ett ärende som behandlas enligt GL 96 §. Efter riksdagsbehandlingen begär undervisnings- och kulturministeriet med stöd av GL 93 § 2 mom. statsrådet om fullmakt att underteckna ansökan om grundande av forskningsinfrastrukturkonsortiet EATRIS som presenteras för kommissionen.

Våren 2012 tillsatte Finlands Akademi en sakkunnigarbetsgrupp för forskningsinfrastrukturer, den s.k. FIRI-sakkunnigarbetsgruppen, vars uppgift bl.a. var att ge ministeriet rekommendationer om Finlands deltagande i internationella forskningsinfrastrukturer och i vilken omfattning utgifter i anknytning till detta kan betalas ur forskningsinfrastrukturmomentet som förvaltas av Finlands Akademi (29.40.22). Under sitt möte den 22 april 2013 har FIRI-sakkunnigarbetsgruppen rekommenderat att Finland deltar i EATRIS ERIC och att Finlands Akademi bereder sig på att finansiera kostnader som Finlands medlemskap medför enligt sin finansieringsandel ur nämnda moment. Instanserna som medverkar i den nationella EATRIS ERIC-verksamheten, Helsingfors universitet (samordnande enhet), Östra Finlands universitet, Tammerfors universitet, Åbo universitet och Teknologiska forskningscentralen VTT har förbundit sig vid att var för sig enligt överenskommelse svara för den självfinansieringsandel som finansieringen som beviljas ur Finlands Akademis forskningsinfrastrukturmoment förutsätter.

FIRI-sakkunnigarbetsgruppens behandling 22.4.2013

Sektionen för rättsärenden (EU 35), skriftligt förfarande 3—7.5.2013

Sektionen för forskning och innovationer (EU 20), skriftligt förfarande 15—21.5.2013

Kommittén för EU-ärenden, skriftligt förfarande 23—24.5.2013

Helsingfors universitets utlåtande 29.4.2013 och 29.5.2013

Östra Finlands universitets utlåtande 13.5.2013 och 28.5.2013

Tammerfors universitets utlåtande 7.5.2013 och 22.5.2013

Åbo universitets utlåtande 7.5.2013 och 22.5.2013

Teknologiska forskningscentralen VTT:s utlåtande 12.5.2013 och 22.5.2013

6 Statsrådets ståndpunkt

Statsrådet anser att Finlands anslutning till EATRIS ERIC stärker den finländska forskningens kvalitet och internationella genomslagskraft, skapar nya möjligheter för att utnyttja resultaten av basforskning för att främja befolkningens hälsa samt stödjer uppkomsten av nya innovationer och produktionsverksamheten. Därmed är det förenligt med Finlands intressen att ansluta sig.

Statsrådet föreslår att Finland ansluter sig till EATRIS ERIC som grundande medlem eller så fort det är möjligt enligt tidtabellerna.

Final version of the EATRIS ERIC statutes for the step 2 ERIC application

EATRIS

European Infrastructure for Translational Medicine

EATRIS ERIC
STATUTES

FINAL VERSION FOR STEP 2 ERIC APPLICATION
4 DECEMBER 2012

Statutes of the European Advanced Translational Research Infrastructure in Medicine European Research Infrastructure Consortium (EATRIS ERIC)

Final version of the EATRIS ERIC statutes for the step 2 ERIC application

Preamble

The Members, while recognizing the important role for the national centres and their translational research capacities as organized through the EATRIS ERIC infrastructure;

Having the aim to improve translational biomedical research by developing a European advanced translational research infrastructure consisting of key preclinical and clinical facilities and translational expertise necessary to support the development of new preventive, diagnostic and therapeutic strategies of biomedical research and development for providing people with better healthcare;

Having the aim to provide access to the European advanced translational research infrastructure with the objective to realize a significant impact on healthcare and make a significant contribution to the advancement of the tools and technologies that drive translational science;

Recognizing and elaborating on the results of the EATRIS Preparatory Phase project, funded by the European Commission and the progress made during the Transition Phase of EATRIS;

Deciding to establish the European Advanced Translational Research Infrastructure in Medicine European Research Infrastructure Consortium (EATRIS ERIC) – as an outcome of the Transition Phase of EATRIS;

Have therefore agreed upon the following provisions:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Name, seat, location and working language

1. There shall be a distributed European Research Infrastructure called 'European Advanced Translational Research Infrastructure in Medicine', hereinafter referred to as 'EATRIS'.

2. EATRIS shall have the legal form of a European Research Infrastructure Consortium (ERIC) incorporated under the provisions of Regulation (EC) No 723/2009 of 25 June 2009 and shall be named 'EATRIS ERIC'.

3. EATRIS ERIC shall have its first statutory seat in Amsterdam, the Netherlands.

4. The working language of EATRIS ERIC shall be English.

Article 2

Objectives and Activities

1. The primary objective of EATRIS ERIC is to advance research in translational medicine by providing and facilitating a research infrastructure.

2. EATRIS ERIC is committed to organizing and facilitating the governance and coordination that is required to establish and operate the EATRIS research infrastructure.

3. The EATRIS research infrastructure connects leading European research institutes that dedicate part of their research and development capacities to EATRIS ERIC sharing content, tools and knowledge on matters such as but not limited to:

(a.) biologics and advanced therapies,
such as gene and cell therapies and regenerative medicine;

(b.) biomarkers;

(c.) small molecules;

(d.) molecular imaging and tracers;

(e.) vaccines.

4. EATRIS ERIC shall pursue its principal tasks on a non-economic basis in order to further promote innovation and to enhance the transfer of knowledge and technology. EATRIS ERIC may carry out limited economic activities as long as they do not jeopardize main activities.

CHAPTER 2

MEMBERS

Article 3

Membership and Representation

1. EATRIS ERIC shall have at least three (3) EU Member States as Members, only states and intergovernmental organisations may become a Member and have voting rights.

2. Any Member shall appoint one or two representatives. Two representatives shall together hold one vote.

3. The current Members and their representatives are listed in Annex 1. The Members at the time of submission of the application to the European Commission are referred to as Founding Members.

Article 4

Admission of Members

1. The terms for the admission of new Members are as follows:

(a.) the admission of new Members shall require the approval of the Board of Governors;

(b.) applicants for Membership shall submit a written application to the Chairperson of the Board of Governors describing their financial contribution and other contributions to EATRIS ERIC objectives and activities and how they will fulfil their obligations.

Article 5

Withdrawal of a Member/Termination of Membership

1. No Member may withdraw within the first five (5) years of the establishment of EATRIS ERIC unless the Membership has been entered into for a specified shorter period.

2. After the first five (5) years of the establishment of EATRIS ERIC a Member may withdraw provided a request is submitted to this effect twelve (12) months in advance. A withdrawal can only become effective at the end of a financial year and after the withdrawing Member has fulfilled its obligations.

3. Notwithstanding Article 5.1. a Member may withdraw during the first five (5) years should the Board of Governors decide to raise the thresholds of the annual financial contribution as specified in Annex 2 under e. and f. The Member wishing to withdraw shall request withdrawal within six (6) months of the adoption of the proposal to raise the annual financial contribution. The withdrawal shall become effective at the end of the financial year on the condition that the withdrawing Member has fulfilled its obligations.

4. The Board of Governors shall have the power to terminate a Membership under the following conditions:

(a.) the Member is in serious breach of one or more of its obligations under these Statutes;

(b.) the Member has failed to rectify such breach within a period of six (6) months of notification thereof.

The Member shall be invited by the Board of Governors to present its position on the proposed decision of termination before any decision may be adopted.

5. Members that withdraw or have their Membership terminated have no right to restitution or reimbursement of any contributions made, nor can they lay any claim to the assets of EATRIS ERIC.

Article 6

Rights and Obligations of Members

1. Rights of Members include:

(a.) the right to attend and vote at the Board of Governors;

(b.) the right to participate in the development of strategies, policies, decision making procedures concerning EATRIS ERIC;

(c.) the right of its research community to participate in EATRIS ERIC events;

(d.) the right of its research community to have access to and to receive support from EATRIS ERIC.

2. Each Member shall:

(a.) pay an annual financial contribution as decided by the Board of Governors;

(b.) empower its representatives with the full authority to vote by single vote on all issues raised during a meeting of the Board of Governors;

(c.) create a national centre or infrastructure consortium for the purpose of fulfilling the obligations arising from these Statutes;

(d.) appoint one (1) National Director to represent it on the Board of National Directors;

(e.) provide the necessary technical infrastructure to make access possible;

(f.) promote the uptake of EATRIS ERIC services among researchers in its own country and gather user feedback and requirements;

(g.) support centres in its own country that wish to join the national infrastructure of a Member State participating in the EATRIS ERIC infrastructure.

3. Contributions other than the annual financial contribution may be made by Members individually or jointly in cooperation with other Members, Observers or third parties. Such contributions, in cash or in kind, are subject to approval by the Board of Governors.

4. EATRIS ERIC shall enter into an agreement with the national centres in order to establish the terms and conditions under which the national centres may join the EATRIS ERIC infrastructure and commit to the objectives and activities as described in article 2. The National Director of a Member State shall use its best efforts to coordinate the interaction of its national centres with the EATRIS ERIC infrastructure.

Final version of the EATRIS ERIC statutes for the step 2 ERIC application

CHAPTER 3

OBSERVERS

Article 7

Observer Status

1. States or intergovernmental organizations which are willing to contribute to EATRIS ERIC but are not yet in a position to join as Members may apply for Observer status.

2. The terms for admission as Observers are as follows:

(a.) observers are admitted for a maximum of three (3) years, unless another term is decided by the Board of Governors;

(b.) the admission of Observers requires the approval of the Board of Governors;

(c.) applications shall be made in writing to the Chairperson of the Board of Governors and shall describe how the applicant intends to contribute to EATRIS ERIC objectives and activities.

Article 8

Withdrawal of an Observer/Termination of Observer status

1. Observers may withdraw at the end of a financial year provided they have submitted a request thereto six (6) months in advance.

2. Financial and other obligations must be fulfilled before a withdrawal by an Observer can take effect.

3. The Board of Governors shall have the power to terminate the Observer status of an Observer under the following conditions:

(a.) the Observer is in serious breach of one or more of its obligations under these Statutes;

(b.) the Observer has failed to rectify such breach within a period of six (6) months of notification.

The Observer shall be invited by the Board of Governors to present its position on the proposed decision of termination before any decision may be adopted.

4. Observers that withdraw or have their Observer status terminated have no right to restitution or reimbursement of any contribution made, nor can they lay any claim to the assets of EATRIS ERIC.

Article 9

Rights and Obligations of Observers

1. Rights of Observers include:

(a.) the right to attend the meeting of the Board of Governors without a vote;

(b.) the right of their research community to participate in EATRIS ERIC events;

(c.) the right of their research community to access EATRIS ERIC infrastructure and to receive support from EATRIS ERIC.

2. Observers do not have the right to decide upon the budget under Annex 2.

3. Each Observer:

(a.) shall appoint one or two representatives;

(b.) shall pay the annual financial contribution decided by the Board of Governors;

(c.) shall describe its contribution to the EATRIS ERIC objectives as mentioned in Article 2.

4. Contributions other than the annual financial contribution to EATRIS ERIC may be provided by Observers individually or jointly in cooperation with other Members, Observers or third parties. Such contributions, in cash or in kind, shall be approved by the Board of Governors.

5. An Observer shall empower its representative(s) to fulfil the obligations referred to in Article 9.3. (b) and (c).

6. EATRIS ERIC shall enter into an Observer Agreement with the Observer in order to establish the terms and conditions under which the obligations are to be fulfilled or the contribution is to be made.

CHAPTER 4

GOVERNANCE OF EATRIS ERIC

Article 10

Governance and Management

1. The governance structure of EATRIS ERIC shall comprise the following bodies:

(a.) the Board of Governors;

(b.) the Executive Board.

Article 11

Board of Governors

1. The Board of Governors shall be the highest and ultimate governing body of EATRIS ERIC with full decision-making power. The Board of Governors shall meet at least once a year and shall be responsible in accordance with the provisions of these Statutes for the overall direction and supervision of EATRIS ERIC.

2. EU Member States shall jointly hold the majority of the votes.

3. The Board of Governors shall elect amongst its members a Chairperson and a deputy for a two-(2) year term. The Chairperson and deputy may be re-elected. Unless decided otherwise, the Chairperson shall chair all meetings of the Board of Governors and shall be assisted by the deputy.

4. The Board of Governors shall use their best efforts to achieve consensus on all decisions. Failing consensus, a simple majority of the votes cast shall suffice to pass a decision, except for decisions specified under 4.1., 4.2., and 4.3.

4.1. The Board of Governors shall decide with a majority of at least two-thirds (2/3) of the votes of the Members on decisions to:

(a.) adopt or change the strategies for the development of EATRIS ERIC;

(b.) appoint, suspend or dismiss the Finance Director and the Scientific Director after consultation with the Board of National Directors;

(c.) establish Subsidiary Bodies in addition to the Permanent Bodies;

(d.) adopt or change Standing Orders which describe the mandate and specify the activities of the Executive Board and of the Subsidiary Bodies;

(e.) adopt and amend the annual work programme and the annual budget.

4.2. Decisions of the Board of Governors to terminate a Membership or Observer status, shall require a majority of at least three quarters (3/4) of the votes of the Members.

A member whose Membership termination is to be decided upon shall have no vote in that decision.

4.3. The Board of Governors shall decide with unanimity of the votes of the Members – not counting any abstentions - on decisions to:

(a.) amend the statutes, except for Annex 1;

(b.) wind up EATRIS ERIC.

4.3.1. Unless otherwise agreed, Members shall be informed of the exact wording of amendments to the Statutes and to Annex 2 at least three (3) months before these amendments are put to vote.

4.3.2. Any amendment to the Statutes shall be subject to the provisions laid down in Article 11 of Regulation (EC) No 723/2009 of 25 June 2009.

5. The Board of Governors shall meet and decide validly only if a quorum of two thirds of all the Members of EATRIS ERIC are present or represented.

6. The Board of Governors shall adopt Rules of Procedure for their own operational procedures.

Article 12

Executive Board

1. The Executive Board shall be responsible for the implementation of EATRIS ERIC and for supporting the Board of Governors. The Executive Board shall be accountable solely to the Board of Governors.

2. The Executive Board shall perform its duties as determined by the Board of Governors and shall prepare its own internal procedures of organisation, meetings and the way the Finance and Scientific Director shall work together in the Rules of Procedure, to be submitted for approval by the Board of Governors.

3. The Executive Board shall consist of the Finance Director and the Scientific Director.

4.1. The Finance Director shall be the legal representative of EATRIS ERIC, shall represent EATRIS ERIC in any litigation and shall be responsible for the (day-to-day) operational management of EATRIS ERIC.

4.2. The Scientific Director of EATRIS ERIC shall be responsible for the strategic scientific development and all operational scientific matters of EATRIS ERIC.

5. The Directors of the Executive Board may serve for a term of up to five (5) years to be decided by the Board of Governors. After the initial term the Board of Governors will decide on any extension. The procedures for the selection and appointment of Directors are laid down in Rules of Procedure adopted by the Board of Governors.

Article 13

EATRIS ERIC Coordination and Support Office

1. EATRIS ERIC Coordination and Support Office is the central management and daily operations office of EATRIS ERIC and assists the Board of Governors. It is managed and its staff is recruited by the Finance Director in consultation with the Scientific Director.

2. The EATRIS Coordination and Support Office is accommodated at the premises of EATRIS ERIC which are located at its statutory seat.

Chapter 5

SUBSIDIARY BODIES

Article 14

Permanent Subsidiary Bodies

1. EATRIS ERIC has the following Permanent Subsidiary Bodies:

(a.) the Board of National Directors;

(b.) the Scientific Advisory Board.

2. The Board of Governors may establish other Subsidiary Bodies if deemed necessary for the functioning of EATRIS ERIC.

Article 15

Board of National Directors

1. The Board of National Directors shall oversee the coordination of the implementation of the strategies laid out by the Board of Governors. The Board of National Directors is responsible for all national scientific activities related to EATRIS ERIC and shall maintain coherence and consistency across EATRIS ERIC and collaboration between the Members.

2. The Board of National Directors shall consist of the National Directors appointed by the Members.

3. The members of the Board of National Directors shall elect amongst its members a Chairperson and a deputy for a two- (2) year term with the possibility of re-election in conformity with the procedures laid down in Rules of Procedure.

4. The Board of National Directors shall propose the Rules of Procedure and adopt them after approval by the Board of Governors for their internal operational procedures.

5. The Board of National Directors shall perform the activities as determined by the Board of Governors in Standing Orders.

6. The Board of National Directors selects the members of the Scientific Advisory Board subject to approval by the Board of Governors.

Article 16

Scientific Advisory Board

1. The Scientific Advisory Board consists of independent and internationally recognized scientists involved in biomedical translational research acting on their personal title and strategic experience.

2. The Scientific Advisory Board offers advice on request to the Board of Governors and may be consulted by the Executive Board and the Board of National Directors on all scientifically and technologically relevant matters including questions regarding the EATRIS ERIC research agenda, scientific strategies and the annual working programme.

CHAPTER 6

FINANCE & REPORTING

Article 17

Budgetary Principles and Accounts

1. The financial year of EATRIS ERIC shall begin on 1 January and shall end on 31 December of each year.

2. EATRIS ERIC funds may be used solely for purposes as laid down in these Statutes.

3. All items of revenue and expenditure of EATRIS ERIC shall be included in estimates to be drawn up for each financial year and shall be recorded in the annual budget. The annual budget shall be in compliance with the principles of transparency.

4. The accounts of EATRIS ERIC shall be accompanied by an audited report on the budgetary and financial management of the financial year. EATRIS ERIC shall produce an annual activity report, describing, in particular, the scientific, operational and financial aspects of its activities. The report shall be approved by the Board of Governors and transmitted to the European Commission and relevant public authorities within six (6) months of the end of the corresponding financial year. This report shall be made publicly available in full or in part.

5. EATRIS ERIC shall be subject to the requirements of the applicable law as regards preparation, filing, auditing and publication of accounts.

6. EATRIS ERIC shall ensure that the appropriations are used in accordance with the principles of sound financial management.

7. EATRIS ERIC shall record the costs of and revenues from its economic activities separately.

8. EATRIS ERIC shall inform the European Commission of any circumstances which threaten to seriously jeopardize the achievement of EATRIS ERIC tasks or deter EATRIS ERIC from fulfilling requirements laid down in the Council Regulation on the Community legal framework for an ERIC.

Article 18

Liability

1. EATRIS ERIC shall be liable for its debts.
2. The Members' financial liability towards EATRIS ERIC's debts shall be limited to each individual Member's annual financial contribution.

3. EATRIS ERIC shall take out appropriate insurance to cover the risks of liability specific to the construction and operation of EATRIS ERIC.

CHAPTER 7

POLICIES

Article 19

Agreements with third parties

1. In cases where EATRIS ERIC deems it beneficial, it can enter into agreements with third parties.

Article 20

Intellectual Property

1. The term Intellectual Property shall be understood according to Article 2 of the Convention Establishing the World Intellectual Property Organization signed on 14 July 1967.

2. The Board of National Directors shall provide for common principles and policies for Intellectual Property as laid down in Rules of Procedure and to be approved by the Board of Governors.

3. The Board of National Directors may conclude agreements with the national centres and infrastructure consortia within the EATRIS research infrastructure in order to ensure that these entities as well as third parties have access to the scientific knowledge of the EATRIS research infrastructure.

Article 21

Access Rights

1. EATRIS ERIC shall ensure as a general rule open access to services and infrastructures supporting and promoting excellence in translational research as well as a culture of 'best practices' through training activities.

2. EATRIS ERIC shall provide guidance for users of EATRIS infrastructure to best ensure that research which has been undertaken using the resources of the EATRIS infrastructure recognizes and respects compliance with any property, personal privacy, ethical and data owner's protection rights as well as secrecy and confidentiality obligations as defined in Rules of Procedure, further ensuring that users agree or agree to comply with access terms and conditions, security arrangements for the internal storage and handling of (bio)materials and handling of information of research institutions participating in EATRIS infrastructure.

3. The criteria and procedures that provide or restrict access to EATRIS ERIC infrastructure data and tools will be defined in Rules of Procedure and decided by the Board of Governors after advice from the Board of National Directors and the Scientific Advisory Board.

Article 22

Scientific Evaluation Policy

1. EATRIS ERIC will provide access to its translational infrastructure to projects that have the most potential for making a significant impact on health care or a significant contribution to the advancement of the tools and technologies that drive translational science.

2. The scientific evaluation process of projects requesting access to the EATRIS ERIC infrastructure will consider scientific merit, unmet medical need, eligibility and translational potential, and will be based upon transparency, fairness and impartiality. Said process will be approved by the Board of Governors and laid down in Rules of Procedure.

3. The scientific evaluation of projects within the EATRIS ERIC infrastructure will consider scientific merit, unmet medical need and translational potential based upon transparency, fairness and impartiality and will be further described by the Board of Governors and laid down in Rules of Procedure.

Article 23

Dissemination Policy

1. EATRIS ERIC shall take all appropriate action to promote the infrastructure and its use in research and education.

2. EATRIS ERIC shall promote the dissemination and sharing of results obtained by national and international research activities.

3. Without prejudice to any property rights EATRIS ERIC shall request its users to make their research results publicly available and to make results available through EATRIS ERIC.

4. The dissemination policy shall describe the various target groups, and EATRIS ERIC shall use several channels to reach the target audiences, such as web portals, newsletters, workshops, presence at conferences, articles in journals and daily newspapers.

Article 24

Employment Policy, including Equal Opportunities

1. EATRIS ERIC is an equal opportunity employer. Employment contracts shall comply with the national laws of the country in which staff is employed.

2. EATRIS ERIC shall endeavour to select the best candidate on a non-discriminatory basis, regardless of background, nationality, religion or gender, reflecting contributions made by Members, without prejudice.

Article 25

Procurement Policy

1. EATRIS ERIC shall treat procurement candidates and tenderers equally and without discrimination, regardless of whether or not they are based within the European Union. The EATRIS ERIC procurement policy shall respect the principles of transparency, non-discrimination and competition. The Board of Governors shall adopt Rules of Procedure defining all necessary details on exact procurement procedures and criteria.

2. The Executive Board shall be responsible for all EATRIS ERIC procurement. All tenders shall be published on the EATRIS ERIC website and in the Members' and Observers' territories. For procurement amounts higher than € 200,000.- EATRIS ERIC shall follow the principles of the current EU Public Procurement Directive and subsequent applicable national legislation. The decision to award procurement shall be published and include a full justification.

Article 26

Tax Exemption

1. Tax exemptions based on Article 143(1)(g) and Articles 151(1)(b) of Council Directive 2006/112/EC and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 shall be limited to the value added tax for such goods and services which are for official use by EATRIS ERIC, exceed the value of €250, and are wholly paid for and procured by EATRIS ERIC. Procurement by individual Members shall not benefit from these exemptions. Without prejudice to paragraph 2 and 4 no further limits shall apply.

2. Tax exemptions shall apply to non-economic activities, not to economic activities.

3. Tax exemptions will be applied to goods and services for the scientific, technical and administrative operations undertaken by EATRIS ERIC in line with its principal tasks. This also includes expenses for conferences, workshops and meetings directly linked to the official activities of EATRIS ERIC. However travel and accommodation expenses will not be covered by tax exemptions.

Article 27

Data Policy

1. The Executive Board shall submit to the Board of Governors for approval Rules of Procedure for data policy in relation to users of EATRIS ERIC infrastructure, the national centres and third parties such as universities, research institutes and industry, with due respect for existing licences.

CHAPTER 8

DURATION, WINDING UP, DISPUTES, SET UP PROVISIONS

Article 28

Duration

1. EATRIS ERIC shall exist for an indefinite period of time.

Article 29

Winding Up

1. The winding up of EATRIS ERIC shall follow upon a decision by the Board of Governors.

2. Without undue delay and in any event within ten (10) calendar days of the adoption of the decision to wind up EATRIS ERIC, EATRIS ERIC shall notify the European Commission about the decision.

3. Assets remaining after payment of EATRIS ERIC debts shall be apportioned among the Members in proportion to their accumulated annual contribution to EATRIS ERIC.

4. Without undue delay and in any event within ten (10) days of the closure of the winding up procedure, EATRIS ERIC shall notify the Commission thereof.

5. EATRIS ERIC shall cease to exist on the day on which the European Commission publishes an announcement to that effect in the Official Journal of the European Union.

Article 30

Applicable Law

1. EATRIS ERIC shall be governed, by precedence:

(a.) by EU law, in particular Regulation (EC) No 723/2009 of 25 June 2009;

(b.) by law of its statutory seat in case of a matter not covered or only partly covered by EU law;

(c.) by these Statutes.

Article 31

Jurisdiction

1. The Court of Justice of the European Union shall have jurisdiction over litigation among the Members in relation to EATRIS ERIC, between Members and EATRIS ERIC and over any litigation to which the EU is a party.

2. EU legislation on jurisdiction shall apply to disputes between EATRIS ERIC and third parties. In cases not covered by EU legislation, the law of the statutory seat of EATRIS ERIC shall determine the competent jurisdiction.

Article 32

Language and availability of the Statutes

1. At any point in time the valid version of the Statutes will be publicly available on the EATRIS ERIC website and at the statutory seat.
2. These Statutes shall be deemed authentic in all official language versions of the Members listed in Annex 1. In addition these Statutes shall also be deemed authentic in the official language versions of the EU Members not listed in Annex 1. No language version shall prevail.
3. Translation of the original version of the Statutes and of amendments that are published in the Official Journal shall be the prerogative of the European Commission. When translations are not provided for by the European Commission they will be provided by EATRIS ERIC Coordination and Support Office.

Article 33

Set-Up Provisions

1. A constitutional meeting of the Board of Governors will be called by the host country as soon as possible but no later than within forty-five (45) calendar days of the European Commission´s decision to set up EATRIS ERIC enters into force. Without prejudice to paragraph 2 no decisions shall be taken by the Board of Governors before at least five (5) Members have joined EATRIS ERIC.

2. The host country shall notify the Founding Members of any specific urgent legal action that needs to be taken on behalf of EATRIS ERIC before the constitutional meeting is held. Unless a Founding Member objects within five (5) working days of being notified, the legal action will be carried out by a person duly authorized by the host state.

3. The Members agree that as of the establishment of EATRIS ERIC, its bodies act in accordance with the Standing Orders and Rules of Procedure as approved by the EATRIS Governing Board during the EATRIS Transition Phase.

Final version of the EATRIS ERIC statutes for the step 2 ERIC application

Annex 1 - LIST OF MEMBERS AND OBSERVERS

This annex lists the Members and Observers, and the entities representing them.

Members

Country or Intergovernmental organisation	**Representing entity (i.e. ministry, research council)**
The Kingdom of Denmark	Danish Agency for Science, Technology and Innovation (DASTI)
Italian Republic	Istituto Superiore di Sanità (ISS)
The Kingdom of the Netherlands	Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie (ZonMW)
Czech Republic	Ministry of Education, Youth and Sports (MEYS)

Observers

Country or Intergovernmental organisation	**Representing entity (i.e. ministry, research council)**
French Republic	Commissariat à l'Energie Atomique et aux Energies Alternatives (CEA)

Annex 2 - ANNUAL FINANCIAL CONTRIBUTION

Financial Commitment for the first five years

For the initial 5-year period after the establishment of EATRIS ERIC the principles for the financial commitment shall be as follows:

(a) Initial commitment for Founding Members is 5 years (no initial commitment for Observers);

(b) Founding Members can sign up for less than 5 years subject to a 25% increase in the annual contribution. The excess will be refunded if the Member completes the 5 years;

(c) The initial financial contribution for EATRIS ERIC year 1 is based on the agreed 5-year budget excluding any uncertain income source (e.g. the income from user fees) and a minimum of 5 Founding Members;

(d) The Netherlands will pay an additional hosting contribution of € 500,000.- in 2013, 2014, 2015. After 2015 the Netherlands will pay an additional hosting contribution of € 50,000.

(e) No Founding Member that has made a 5-year commitment will pay more than €140,000.- per year (maximum threshold);

(f) The minimum membership contribution will not be lower than € 50,000.- per year regardless of the number of Members and regardless of any income generated by EATRIS ERIC (minimum threshold);

(g) The financial contribution for EATRIS ERIC year 2 is based on the agreed 5-year budget minus the net result from income in EATRIS ERIC year 1. The financial contribution for EATRIS ERIC year 3 is based on the agreed 5-year budget minus the net result from income in EATRIS ERIC year 2 etc;

(h) A new Member starts at the financial contribution level it would have paid as a Founding Member in EATRIS ERIC year 1 plus 25%. After accession year 1 it pays the financial contribution set for EATRIS ERIC year 2 plus 25% etc. If the new Members completes a 5-year term, the excess is refunded;

(i) Founding Observers with institutes not participating in all activities of EATRIS and not providing services pay 25% of the annual financial contribution of what they would have paid as Founding Members. A Founding Observer with institutes participating in all activities of EATRIS including providing services shall pay the same annual financial contribution as a Founding Member.

(j) A Founding Observer that pays 25% of the annual financial contribution and that becomes a Member starts at the same level of financial contribution it would have paid as a Founding Member in EATRIS ERIC year 1. After accession year 1 it pays the financial contribution set for EATRIS ERIC year 2 etc. If it completes a 5-year term, the Observer financial contribution is refunded;

(k) A new Observer starts at 25% of the financial contribution it would have paid as a Founding Member in EATRIS ERIC year 1. In year 2 of its accession it pays 25% of what it would have paid in EATRIS ERIC year 2 etc;

(l) If a new Observer becomes a Member it pays the financial contribution it would have paid as a Founding Member in EATRIS ERIC year 1. After accession year 1 it pays the financial contribution set for EATRIS ERIC year 2 etc. If the new Member completes a 5-year term, the Observer financial contribution is refunded;

(m) If new Members or Observers join or if an Observer becomes a Member the financial contribution for that year is recalculated for all Members and Observers;

(n) In all cases mentioned above, the 25% extra financial contribution is held in reserve.

ERIC TECHNICAL & SCIENTIFIC DESCRIPTION

Table of Contents

1. Vision & Mission

1.1 Background - Europe's global competitive position

National governments in the EU and elsewhere note with grave concern that the output of novel healthcare solutions (in the form of diagnostic and therapeutic applications, as well as medical devices) has been stagnating over the past decade, despite substantially increasing investment of human and financial capital from the private sector. Simultaneously, national health authorities face rising healthcare costs, and governments struggle to address the innovation paradox, in which the vast resources dedicated to fundamental research infrastructure and activities are not generating societal health returns to match expectations and the needs of the population.

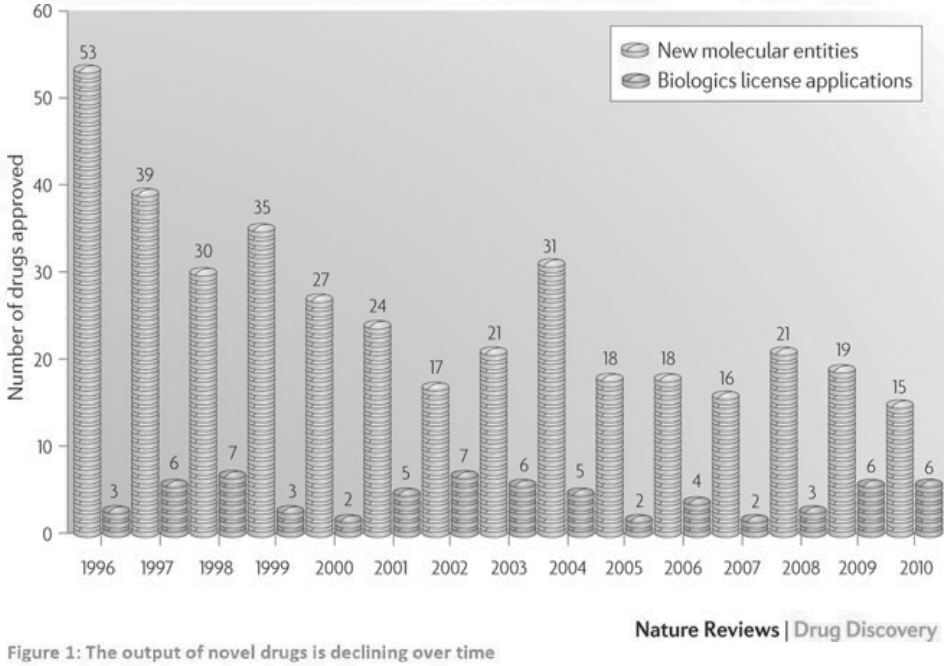


Figure 1: The output of novel drugs is declining over time

Figure 1 shows clearly the general trend of declining output. At the same time the average cost of bringing a new drug to market is estimated at between US$800 million and $1.5 billion, and takes 12-14 years[1]. Both industry and governments see a clear need for significant change to the existing research and development model.

A further cause of concern for European governments is the declining competitiveness of the European pharmaceutical and biotechnology industries. For example, between 1990 and 2008, European R&D investment grew 3.5-fold, compared to 5.6-fold growth in the US. This relative decline is echoed in a reduction in both absolute numbers and output ratio of new chemical entities compared to the US[2]. Moreover, as the fast growing middle-income nations mature away from a purely manufacturing focus and

[1] For more on this subject see 'Research and Development in the Pharmaceutical Industry,' a report by the US Congressional Budget Office, available here: http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf

[2] For more facts and figures about Europe's competitiveness in this sector, please see the website of the European Federation of Pharmaceutical Industries and Associations: http://www.efpia.org/Content/Default.asp?PageID=388

into higher value added industries such as pharmaceuticals, Europe is under further pressure to not only maintain but increase its innovation potential and productivity.

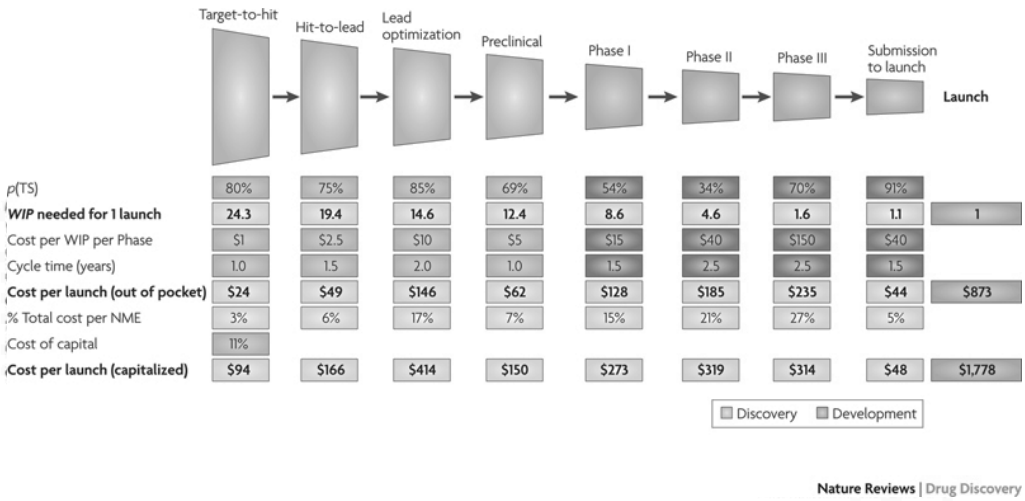


Figure 2: The high costs and attritions rates in the discovery and development pipeline

1.2 Deficiencies in the current R&D model

In its existing form, pharmaceutical R&D suffers from the double-edged sword of a high attrition rate, combined with a structure that does not facilitate efficient deployment of resources along the value chain. That is, candidate products that should otherwise be abandoned or modified are being pursued further into the highly costly and time-consuming later clinical research stages, as shown by figure 2. There are, however, both validated and emergent technologies that can serve to ameliorate the attrition rate, by reducing risk in two ways:

1) Gaining deeper insight into both the disease mechanism mediated by the target under investigation, and the mechanism of action of the candidate therapeutic on the target. These techniques facilitate improved advancement of fundamental disease understanding into the applied knowledge necessary to develop effective therapeutics – 'translational' research referring to the transition from fundamental to applied;
2) Use of technological tools, such as molecular imaging techniques, to gain vital early effectiveness information, such as target engagement within the safe exposure range. Although these methods do not provide the comprehensive insight necessary to determine a product's potential, they are an effective means of creating early milestones in which ineffective candidates can be discovered and abandoned much earlier (many months and millions of Euros earlier) than would otherwise occur within the traditional R&D value chain.

2. Mission – advancing translational research in Europe

It is with the above considerations in mind that EATRIS has developed its mission for the effective advancement of translational science in Europe.

The EATRIS Mission

EATRIS transforms scientific discoveries into innovative and high impact medicines, diagnostics and medical devices through

European collaborative consortia of academic, industrial and governmental partners.

3. Objectives

EATRIS has two primary long term objectives, developed in order to support achievement of the mission:

***Objective one**: to make academic translational research infrastructure capacity and expertise available* - from members (members here signifying states participating in the ERIC, in accordance with regulation (EC) No 723/2009) in an efficient, effective and equitable manner to third parties, in order to advance high quality and clinically promising research projects from around the EU, so that EATRIS can facilitate further optimisation of the pharmaceutical discovery and development process and rejuvenate the pipeline with high potential, clinically relevant projects.

***Objective two**: to support innovation and advancement of the field of translational science* - by facilitating the growth of a translational science community in which technological innovations, best practice and experiences are structurally exchanged, developed, and implemented into practice. The discipline is further supported through the development of a wide range of learning and education options for current professionals and biomedical students.

4. Strategy and scope

4.1 Operational strategy

EATRIS is designed to overcome the fragmentation typical of the research environment, to consolidate knowledge and expertise and to secure continuous funding to help the research community progress a project as efficiently as possible from advanced basic research to first clinical application in humans. Translational research aims to aid the transition from R&D to clinic and ensure that information gained along the way is fed back in both directions to obtain the most efficient research pathway possible. Translational research is thus a two-way process:

- From bench to bedside. Proof of concept is established for a discovery in a pre-clinical setting. This entity is then validated and improved upon to be able to move into clinical trials (Phases I, II and III) and ultimately be brought to clinical application; and
- From bedside to bench. Valuable information may be obtained from clinical trials and clinical experience that can help determine which new questions require further exploration through fundamental and preclinical research. Translational research thus allows feedback from the clinic back to basic research in order to better understand mechanisms of action and improve predictability of responses in patients.

EATRIS links together top translational research institutes in the academic sector, creating consortia with the scope and scale of expertise and capacity to be able to substantially increase access to the large and costly infrastructure contained therein. At the same time, EATRIS provides a simple, centralised access principle – a 'One-Stop Shop' – that allows quick, fair and transparent access to the services and capacities offered. The central coordination group responsible for access (called Coordination & Support, or C&S) also facilitates the interaction of the consortia, by coordinating the Quality Assurance, regulatory, contracting, intellectual property, project management and education elements of EATRIS, as well as by creating and administering the communications infrastructure and executing the outreach strategies.

4.2 Scope

EATRIS has built its consortia around five technology areas (called Product Groups):

- Vaccines;
- Imaging and Tracers;
- Biomarkers;
- Advanced Therapy Medicinal Products (ATMP) and Biologics
- Small Molecules

These were selected on the basis of discussions with prospective users of translational research infrastructure (academia, SMEs and large biotech/pharma companies), who indicated that there is sufficient demand, and sufficient expertise (albeit fragmented and not readily accessible) to match that demand, in Europe. Furthermore, the output of these areas of activity can contribute significantly to the needs of the healthcare sector and society.

The consortia comprise critical mass in the capacity and range of expertise necessary to be able to provide substantial amount of external user access to the full range of the translational pipeline, which in this case is defined as starting with advanced fundamental (proof-of-principle) to Phase II/IIa clinical trials (proof-of-concept).

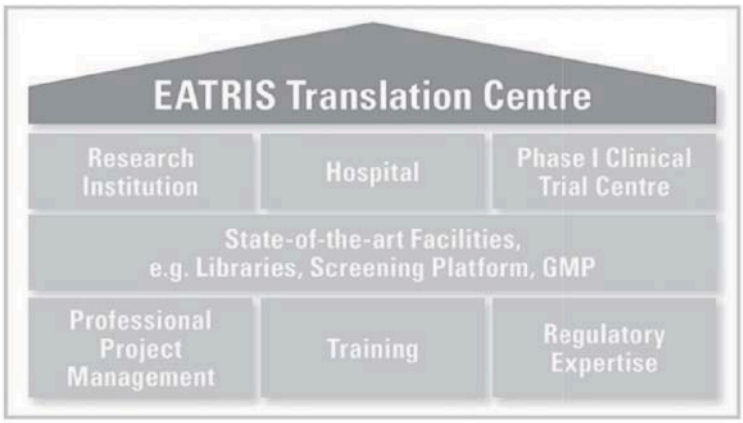


Figure 3: each participating center has a broad range of translational capabilities

4.3 Unique value proposition

EATRIS offers a range of advantages over current practice in Europe for several stakeholders:

4.3.1 Value to European translational biomedical research

The primary benefit of EATRIS will be the availability of efficient access to rare and costly expertise and cutting edge infrastructure for the development of translational projects in the five product group areas. This means that all researchers in Europe (and beyond – there is no statutory geographical limit to access) have the opportunity to further develop their promising early stage projects into high potential clinical phase developing products, whether they are from other academic centers, the private sector or philanthropic/charitable organisations. The only stipulations for access will be based on scientific merit, unmet medical need and translational potential.

This will result in the best research in Europe being paired up with the best infrastructure and expertise for taking it further along the development pipeline. Moreover, EATRIS comprises a comprehensive offering that can seamlessly bring an early stage discovery to proof-of-concept via a single entry portal, using a single application and with one-time negotiation of conditions based on the existence of a set of standard contracts and IP arrangements. Such a complete and efficient access and execution mechanism for

translational research, open to external users, does not exist in Europe to date and in this respect makes EATRIS unique and very valuable.

4.3.2 Value to participating academic centers

EATRIS has a main driving principle the continuing development of European translational science and competitiveness. In order to achieve sustainable growth and innovation, a key underlying condition is the active collaboration of participating institutes and related stakeholders on several fronts:

- Lively and open dialogue about translational science and the environment in which it exists, including regulatory, societal, governmental and reimbursement issues, all of which have direct impact on the field.
- Top priority for the quality assurance and control mechanisms that make EATRIS a by-word for quality. All projects and activities occurring under the EATRIS flag have the highest standards expected of them, as reliability and quality of research execution and its results are an excellent means of reducing risk and uncertainty for the later development and regulatory approval process of products.
- Innovation in the translational tools and platforms, and increasing inter-operability and harmonisation between centers. EATRIS seeks to stimulate constant innovation and the widespread dissemination and adoption of such innovations so that Europe can regain a foothold in the translational science space. Collaboration at this level encourages such activities, with the promise of access to excellent research and best practice for the institutes able to offer the excellence in quality and innovation that EATRIS infrastructure represents.

4.3.3 Value to industry

EATRIS has two primary values for the pharmaceutical and biotech industries (including medical device manufacturers). Firstly, they too have open access to the excellent infrastructure that EATRIS offers, which is predominantly highly capital intensive facilities that are otherwise out of reach for companies, especially the vital motors of economic growth, SMEs.

Secondly, but no less importantly, the result of matching Europe's top infrastructure and translational expertise to the best research projects will be a rejuvenation of the biopharmaceutical pipeline with more high promise, de-risked clinical phase projects. It is at this phase (around Ph. II/IIa) that industry becomes structurally involved in the further development of products, and thus makes EATRIS an important new source of high potential leads for industry. Naturally this will lead to an increase in the number of innovative and high impact healthcare solutions making it into routine clinical use.

4.3.4 Value to society

Society benefits on several fronts:

- EATRIS is not driven by an economic imperative, thus will focus also on neglected and orphan diseases otherwise ignored by industry. Thus patients in Europe and beyond can expect not only a general improvement in the output of innovative medicines, diagnostics and devices, but also a significant improvement in solutions aimed at commercially uninteresting patient groups.
- Matching excellent research to excellent facilities and capacities means that expensive, taxpayer funded infrastructure is being optimally deployed, and the fruits of the labour created are channelled to the public institutions involved via the joint ownership intellectual property arrangements of EATRIS. Thus society sees a greater return on investment, represented by improving output and a share of the economic gains. Furthermore, gaps in the existing infrastructure are identified and remedied on a European level via EATRIS, providing a structural mechanism for continuous and efficient development of highly capital intensive European research infrastructure. This will ensure infrastructure capacity is optimally deployed across borders, which will serve to increase European competitiveness as well as resource efficiency.

- Europe has an opportunity to regain lost competitive ground in the sector, by stimulating excellent research, funding top infrastructure and encouraging innovation in a constellation that structurally brings together the strengths of industry, academia and governments. Moreover, EATRIS acts as a forum for honest debate between the three sectors, in order to improve communication, legal and regulatory alignment and competitiveness, and reduce uncertainty for the practitioners of translational science in Europe. Over the long term, this collaborative stance will yield real results.
- Finally, by encouraging learning and education in translational science, EATRIS supports the long term sustainability of the discipline in Europe, and will facilitate further innovation by providing the next generations of top international talent.

5. Structure

EATRIS operates on a 'hub-and-spoke' basis, in which the central hub, the Coordination and Support Office, is responsible for the coordinated operation of the distributed academic research institutes that participate in the infrastructure. This creates a European distributed translational research infrastructure that provides uniform and equitable third party access to state of the art expertise and capacity in translational medicine.

The institutes retain their own legal personality, and thus all activities that take place under the ERIC are formalised in Research Annexes to the consortium agreement, created in advance of commencement of individual research projects. These Annexes clearly indentify goals, activities and responsibilities within individual research projects and thus provide the formal basis for differentiating ERIC (and thus VAT-exempt) activities from the 'regular' institutional activities. Furthermore, EATRIS follows the subsidiarity principle in that the construction and operation of the infrastructure is left to the members.

5.1 Organisational units

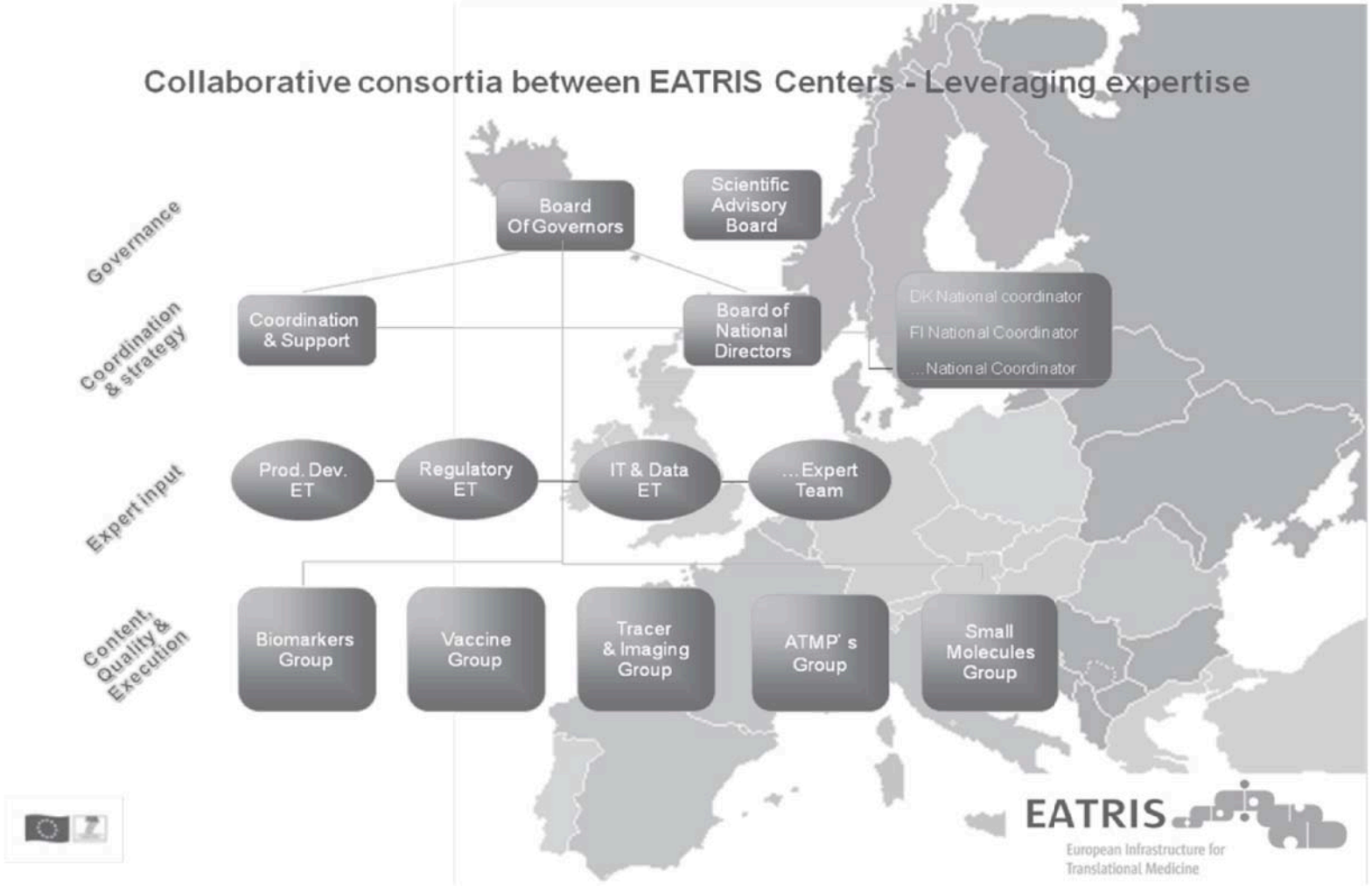
- *Board of Governors* - the ultimate governing authority of the initiative, composed of representatives of the legally entitled entities mandated by each EATRIS ERIC member.
- *Executive Board* - responsible for the implementation and operation of the daily management. The Board of Governors gives general directions to the Executive Board and regarding the specific roles of the Executive Board. The Executive Board consists of the Business & Finance Director, the Scientific Director and the chairperson of the Board of National Directors, expressing the collective responsibility of the Members for representation, execution and synergy to adequately perform and execute translational research within the EATRIS ERIC infrastructure.
- *Board of National Directors* – is composed of representatives from the scientific institutions mandated to oversee all national scientific activities related to the EATRIS initiative. These institutions may or may not be a centre participating in the actual research activities of EATRIS.
- *Scientific Advisory Board* – providing scientific and operational input to C&S and the governing boards, EATRIS will establish an advisory board, comprised of experts from several fields:
    - academia- from EU & international research institutions;
    - industry - from EU & international large and SME pharmaceutical and biotech companies;
    - Related ESFRI initiatives;
    - Patient advocacy groups;
    - Regulatory and governmental institutions.

  Due to the need for in-depth and expert feedback from each of the stakeholder groups, the advisory board will be convened in smaller groups comprised of experts from one or two fields, in order to maximize the depth of the material covered and to keep the sessions focused and manageable.
- *Coordination & Support Office* – located in Amsterdam, The Netherlands, the central hub coordinates access to the infrastructure and creates the boundary conditions necessary for effective and efficient operation of the infrastructure. C&S installs and supports the activities of the expert teams.
- *Expert teams* – regular input from experts in a range of disciplines is necessary to reach and maintain scientific and operational excellence for EATRIS. C&S operates with teams of external experts in their fields - coordinated and assembled when necessary by the relevant personnel within C&S – to provide

tailored advice to questions and issues arising before and during research operations. The areas of activity are: quality assurance, translational project management, product development, regulatory affairs & compliance, and legal & intellectual property.

- *Product Groups* – composed of the research institutions participating in the ERIC research activities, they organize the translational research pipeline and operate around the five core technological areas, (vaccines, imaging & tracers, biomarkers, small molecules and ATMPs. At the moment biologics (eg monoclonal antibodies) form part of the ATMP group, but this may be expanded into its own group in the future. Each product group is composed of several centres, based within multiple members. Individual research institutions may participate in more than one product group.

5.2 Organisational structure



6. Activities

There are two main types of activities:

1) **Infrastructure activities in the translational pipeline** - EATRIS brings "under one roof" critical mass in infrastructure needed to secure successful translational research: high-quality physical resources (so-called bricks), such as state-of-the-art imaging and animal facilities, basic research facilities and Phase I clinical trial centres; Professional scientific and project management ("brains"), to guide translational R&D projects, as well as education and training of scientists, physicians and science-oriented clinicians on translational research. Each of the five product groups have overall guidance and control of the output of these activities.

2) **The organisation and facilitation** - of the translational research chain and the pipeline consortia are key components of translational research and differentiates us from the other Research Infrastructures. EATRIS delivers a range of services to the users being more than just access to the bricks and brains. Therefore the bricks and brains will be "cemented" by connecting them into a full, seamless harmonised pipeline with quality assurance and quality control, access management, training, professional research management for product development and regulatory expertise. Each consortium varies composition per product group, and the composition of consortia within product groups varies per disease specialisation/research project.

6.1 Infrastructure activities

Vaccines

The traditional vaccine development chain follows (i) vaccine formulation, (ii) preclinical validation, (iii) clinical development. Where required, support for antigen/prototype re-validation is provided.

Among the extensive list of services are: (i) vaccine formulation, including antigen(s) production (up and downstream), antigen delivery, adjuvantation and galenics; (ii) establishment of in vitro and in vivo assays for preclinical studies (e.g. validated readouts for humoral and cellular immune responses at systemic and mucosal levels, tests to evaluate effector mechanisms, identification of correlates for protection, potency tests, etc.); (iii) preclinical in vivo validation studies to assess the immunogenicity, efficacy and safety of vaccine products in rodents (e.g. conventional, immunodeficient and humanized mice) and other species (e.g. rats, pigs, non-human primates) up to BSL3 containment, in facilities linked to core immunomonitoring, in vivo imaging, flow cytometry, -omics and histopathology facilities; (iv) GLP certified safety/toxicology; (v) GMP production; (vi) generation, management, coordination and execution of clinical development plans in EATRIS clinical trial centres.

Imaging and Tracers

Molecular imaging has become a vital tool in drug discovery and crucial to contain development costs, speed up the process and increase pipeline output, with several benefits:

- EFFICACY: Used early in the process (Phase I/II) in small, imaging-enabled trials, dead-end compounds can be eliminated before vast trial expenditures are made.
- DEVELOPMENT SPEED: Clinical dose finding studies can be performed much more rapidly and the number of volunteers in Phase I can be reduced by up to 80
- PERSONALISED MEDICINE: disease delineation and prognostication, followed by confirmation and quantification of targeting, and early response/outcome monitoring. This can be achieved in patient cohorts displaying heterogeneous disease characteristics, identifying cohorts with the highest benefit.
- MECHANISM OF ACTION: molecular imaging is an essential tool for understanding disease mechanisms, by visualising and allowing quantification of critical disease targets and molecules.

The high-end tracer development and (molecular) imaging pipeline comprises the following key components: (1) a target re-validation facility to confirm the status and biological importance of a disease-specific target, (2) a tracer production facility comprising cyclotrons and hot cells for the preparation of PET tracers as well as labs for preparation of other types of disease-specific contrast agents as used in SPECT,

MRI and optical imaging (contrast agents collectively called "tracers"), (3) animal facilities using animal models of relevance for studying major as well as orphan human health problems in the field of oncology, neurology, immunology, cardiovascular and infectious diseases, and others (4) labs for tracer metabolite analysis to study metabolism and degradation of tracers, thus facilitating the quantification and interpretation of the imaging signals, (5) preclinical imaging labs comprising PET, SPECT, (ultra high field) MRI, US, optical and hybrid scanners for (quantitative) assessment of tracer kinetics in various biological and pathological models, (6) GMP facilities and hot cells EU certified for tracer production for "human use", (7) clinical trial centers with access to patient cohorts representing major as well as orphan human health problems (8) clinical imaging centers comprising PET, SPECT, (ultra high field) MRI, US, optical and hybrid scanners for optimal and reproducible acquirement of multimodality imaging data, and (9) data analyses centers for optimal and standardized handling, processing and storage of multimodality imaging data, and potential coupling of these data to other sets of data using appropriate ICT infrastructures. Tracer kinetics is analyzed using an array of compartment and non-compartment methods. A key issue is data sharing to facilitate multi-center trials within the EATRIS network. Users may make use of the whole imaging pipeline, or of some defined key elements.

Biomarkers

EATRIS Biomarkers product group offers a standardized platform for European biomarker development, particularly in areas that are becoming increasingly important, but are underdeveloped by the industry, such as multiplexed and tissue- and imaging-based, morphologically oriented biomarker development. EATRIS also offers translational, standardized access to unique capabilities (patient materials, biobanks, and clinical data) that exist in the participating centres and academia in general. These are important for private sector users with diagnostic development pipelines. In particular, the use of standardized biobanks is facilitated by collaboration with the European-wide Biobanking infrastructure BBMRI. Furthermore, a key issue is data sharing, to facilitate multi-centre trials within the EATRIS network. This is accomplished via an IT infrastructure and web microscopy, distributed to key EATRIS parties for joint standardized development projects on biomarkers. Users may make use of the whole biomarker pipeline, or some defined key elements. Depending on the nature of biomarker and the starting point, the output of the EATRIS biomarker effort is:

- Identification of the critical path required to advance a new biomarker towards a product;
- Validation of the biomarker in independent sample cohorts, initial assessment of the sensitivity, specificity, with standardized technologies;
- Prototype diagnostic assay development, standardisation and optimisation of the quality control parameters;
- Validation of the prototype diagnostic assay and development of a commercial plan, including industrial participation and regulatory steps required.

ATMP & Biologics

The current development of ATMP is limited by their intrinsic complexity (from recombinant nucleic acids to artificial organs), their complex interactions (cell to cell and to the organism), and by the multiplicity of mode of action, making the definition of identity, potency and dose a major interdisciplinary challenge. However, the participating EATRIS centres have already accumulated a vast experience in various aspect of the development of ATMP as demonstrated by the large number of different products already in clinical trials:

1. Cancer Immunotherapies based on autologous dendritic, antigen-specific T-cells/NK cells;
2. Gene therapies for immune-deficient patients;
3. Control of Graft-versus-host disease (GVHD) in recipients of allogenic hematopoietic stem cell transplantation by infusion of mesenchymal cells or donor engineered T cells;
4. Restoration of articular cartilage or bone structures using autologous chondrocytes /mesenchymal cells
5. Ex vivo antigen-specific T-cells for the control of infectious diseases or as anti-tumour treatment
6. Decellularised tissues as substrate for tissue engineering products.

This Product Group has special facilities required for the GMP production and GLP toxicity testing of these products. They have developed innovative analytical tools, such as: a.) Identity testing of the final product including the developing of methodology for tissue engineering constructs replicating organ functions; b.) Potency assays for the definition of dosage and for comparability studies including the definition of validated biomarkers for clinical studies; c.) Innovative animal models required for a meaningful efficacy and safety assessment in vivo; d. Gene Therapy vectors for efficient and specific gene transfer to target cells.

Small Molecules
Typically optimization of a lead compound requires successive steps of chemical synthesis which are heavily influenced not only by the results of the original screening procedures, but also by the data obtained after more complex and intermediate assays. In today's academic research environment, various structural and infrastructural shortcomings severely compromise and/or retard the translation of scientific findings into clinical applications. Other deficits are clearly linked to the specificity of the development chain.

In order to be able to provide integrated transnational services, the group has harmonised compound screening procedures, improved the quality and quantity of the available technologies across all EATRIS centres for in vitro, in vivo and toxicity testing. We make use in first instance of profiling assays that can be used for high throughput screening, based on e.g. automated image analysis of phenotypic effects, and in silico algorithms to predict effectiveness of the compounds. For all assays SOPs are written, with several pilot studies to assess the quality and quantity of these assays.

The group incorporates the possibility to develop a biomarker to guide application of targeted therapies in close collaboration with the Product Group Biomarkers. With Product Group Imaging/Tracers there is two-way collaboration. For the in vitro and in vivo models we use a pipeline of developing compounds with an imaging linker , including imaging biomarkers (based on tracer compounds) for the use in early clinical development phases to: a) confirm drug distribution (i.e. brain penetration); b) optimize posology; c) confirm early proof of concept; d) help identify patients who are most likely to benefit, and e) make the transition to phase III clinical trials more valid, rapid and improve the success rate. In parallel there is a platform for in vivo testing. The available animal models are catalogued and a SOP for in vivo and toxicity testing in the different types of animal models are written and tested.

This group also focuses on innovative therapeutic approaches such as the use of bioactive peptides and nanoparticles for brain drug targeting. Peptides are short aminoacid polymers with a defined primary structure and can be easily synthesized with FMOC chemistry. This type of compounds has enormous potential, particularly within the frame of targeted therapy. Moreover, a growing number of engineered nanoparticles (NP) are now being used in theranostic applications. This avenue will also form an area of interest.

6.2 Coordination and facilitation activities

In order to be able to offer critical mass in translational research via distributed consortia of centers of excellence, an important element of the effective operation of EATRIS is to create the underlying conditions necessary for collaboration. C&S will coordinate the integration of the centres and provide a single entry portal for access to all users to provide swiftly and effectively access to the centres. Via C&S, EATRIS maintains harmonised and common procedures and agreements, and ensure that the services supplied to the sponsor will be under a common Quality Assurance system and in agreement with the requirement for the Marketing Authorization Application of medicinal Product or equivalent for diagnostic or medical devices, and all personnel involved are trained and provided with professional assistance.

Based on a careful analysis EATRIS has selected 5 expert activities that are essential for the services delivered by the product groups and thus for the quality and sustainability of EATRIS. C&S coordinates and administers these activities. These 5 expert groups, discussed in more detail below, provide vital knowledge and expertise into the translational process that is often lacking within the institutions themselves. These areas

of expertise are crucial to the success of the projects as they provide legal, regulatory, logistic, contractual and project management input into the complex mix of activities. Thus each consortium and project has access to the latest knowledge in all fields relevant to translational development, and is mandated to follow the advice of the expert groups.

Quality Assurance and Regulatory Affairs

EATRIS facilitates translational research and development of new pharmaceutical entities. In the context of making these entities available for the treatment or prevention of disease, altering physiological functions or making a diagnosis in humans, R&D activities are tightly regulated on a European level. Thus it is stipulated for a consortium like EATRIS that every centre taking part in the development complies with the regulations corresponding to their field of work (e.g. Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) or Good Clinical Practice (GCP) requirements). Moreover, the requirements increase as a product moves through the development chain into the direction of marketing authorization (e.g. the requirements on manufacture (validation, qualification of production and quality control (QC)) tighten when the product moves from Phase I to Phase II and subsequently Phase III clinical testing). Thus, it is a critical success factor that a super-ordinate body assures and continually tracks that all requirements are met at each stage of development and that updated or new requirements are perceived (e.g. new regulations on "first in man" clinical trials following the TGN1412 incident). Even more, it needs to assure and control that all development partners comply with the requirements. It is the responsibility of the Quality Assurance and Regulatory Affairs group to run such a unit, with the aim to facilitate pharmaceutical R&D activities enabling a developed product to, from a regulatory and QA perspective, be approvable according to EU standards.

The unit is run by a Head of the Quality, who is not be involved in the operative work of EATRIS and not be a member of an operative institution, in order to eliminate potential conflicts of interest. This function is equipped with the competence and authority to assert above mentioned tasks. The Unit's work is supported with input from personnel from the product groups. These personnel contribute to the content of the documentation during the set-up of the Unit and afterwards to a specific task or process that needs to be established. In doing so, the QA/QC Unit implements the expertise and existing knowledge on QA/QC processes already available in the Centres. The unit established written policies. This includes general QA/QC policies be laid down in e.g. a Quality Manual. To structure, regulate and document its processes, a Standard Operating Procedure (SOP)-System is established. For providing a high degree of transparency of its work, general provisions and policies are made publicly available.
The regulatory environment is not constant, but dynamically moving and permanently adapting to the state of the science and technology. In this interaction between QA/QC is of vital importance to provide input to improve regulation. Especially innovative products tend to become more tightly regulated as scientific, regulatory and technical knowledge increases (e.g. regulation on “first in man” clinical trials following the TGN1412 incident). Therefore, the QA/QC Unit needs to perform regulatory intelligence in order to be up-to-date and to relay this information to the centres (see below). This knowledge is structurally transferred to the product groups via written manuals and SOPs and an active training schedule training to ensure continual development of the understanding of pharmaceutical QA, as well as knowledge on the changing regulatory environment.

User access

A cornerstone of the EATRIS mission is to offer fast, fair and transparent access to Europe's top translational research infrastructure and expertise. C&S coordinates the administrative, scientific, digital, legal (including intellectual property) and financial framework necessary to support the access and transaction process, and allows the participating service providers to carry out their services.

In order for external users to easily interact with and collaborate with EATRIS and its participating institutions, there are SOPs and legal and communications documents that facilitate third parties to apply for and gain access to services:

i) Easily find and understand the access procedures, guidelines and conditions for making use of EATRIS services;
ii) Interact with EATRIS;
iii) Apply for access in a transparent, simple and resource-efficient process;
iv) Be subject to a fair scientific and technical appraisal of their application by an independent review committee composed of experts in the relevant fields, within a reasonable amount of time;
v) Have adequate and timely access to a transparent and fair appeal procedure; and
vi) Be subject to an efficient transaction process for successful candidates allowing successful negotiation of the research project including financial considerations, with the ready availability of contracts. It is envisaged that some flexibility in the conditions of access will be permitted to allow for the heterogeneous nature of the inputs and expected outputs, based on the available precedents and templates.

The criteria for access will be based only on scientific merit, unmet medical need and translational potential. It is of no relevance what the nature (i.e. academic or private sector), the nationality or the background of the applicant is. EATRIS will provide access to its translational infrastructure to the projects that have the most potential for making a significant impact on healthcare or a significant contribution to the advancement of the tools and technologies that drive translational science.
In order to maximize fairness and impartiality, the user selection committee is predominantly composed of experts with no affiliation to the participating centers, and in order to maximize transnational reach and transparency, all calls and their guidelines, including instructions for application, appeal procedures and all relevant deadlines, are published on the EATRIS website and disseminated via partner institutions in the EU.

There are several access modes that will be used by EATRIS. Each of these will have different conditions of access, such as financial and intellectual property requirements, or in the disease area called. Individual SOPs are made according to the differing conditions of these call types. Due to the variety in funding models available there are different modes, such as:

i) ERA-NET plus calls funded by multiple member states;
ii) JPI type calls funded by multiple stakeholders;
iii) Individual or shared calls funded by patient advocacy groups, philanthropic organisations or other disease-specific stakeholders; and
iv) 'Anytime' access for users capable of fully funding the research project themselves.

The second objective of user access activities is to ensure that the product groups are operations-ready for service provision. This is achieved by creating the boundary conditions necessary for the participating service providers to interact with C&S, partners (other service providing institutions within the product group) and third party users on a structural, ongoing basis during the operations of EATRIS. This includes:

i) Consortium agreements;
ii) Research annex templates including budget schedules;
iii) Materials transfer agreements;
iv) Confidential disclosure agreements;
v) Intellectual property framework;
vi) Services pricing schedules; and
vii) Infrastructure for research project participant interaction and communication as an interactive website.

C&S is responsible for the creation and administration of these boundary conditions, with extensive input from experts residing within members and their participating centers of excellence.

Outreach, training and education
Communication and education are vital elements to the success of EATRIS, both internally and towards external stakeholders. There are several objectives:

- to facilitate the training and transfer of knowledge between and across all EATRIS partners and their employees, including the employees of the national centers who will participate as linked third party;
- to establish a translational science community, along with the necessary infrastructure to facilitate regular and unimpeded interaction of its members and the wider global (scientific) community;
- to disseminate and promote EATRIS services and results to all stakeholders, in order to act as an engine to stimulate lively debate, encourage innovation and increase access to potential users for marketing purposes;
- to facilitate of strategic partnering, such as related Biological and Medical Sciences Research Infrastructures, including BBMRI, ECRIN, TRANSVAC, EU-OPENSCREEN, ELIXIR, Euro-BioImaging;
- branding of EATRIS

The translational community includes all stakeholders, ranging from universities, research hospitals, research organisations to companies, and ties translational research and infrastructure. EATRIS serves as a communication, dissemination and training channel for the knowledge and results obtained. The aim of EATRIS is to facilitate translational research and development of new pharmaceutical entities. An important aspect of effective translation is mediated by fluent and seamless interaction and communication between the various and highly divergent functional groups involved. It is thus a critical success factor to develop a common process and to stimulate multi-disciplinary teamwork. At the operational level, employees should speak the language/jargon of their colleagues from all functional working groups and respect their activities and contribution to the whole translational medicine development process.

It is also critical to the long-term success and advancement of translational science that an adequate range and depth of training programs are available, in order to encourage the continuing professionalization of translational science and nurture the translational scientists of the future. Thus alongside the training of active professionals in the EATRIS centers in conducting effective multi-disciplinary translational research, translational science curricula are also offered, created on a collaborative platform with the IMI initiative EMTRAIN, with the input of the experts of the product groups.

Clinical development and partnering: EATRIS brings projects to proof-of-concept, thus no further than phase II/IIA clinical trials. In order for these projects to culminate in entry to clinical practice, EATRIS actively seeks partners that have the expertise and resources to complete the clinical development and marketing authorization process. Partnerships can be with private sector pharmaceutical firms, or (generally in the case of orphan or neglected indications) open innovation in style, partnering with ECRIN for execution of late-stage trials and funded by public grants or charities and philanthropic organizations.
Whatever the partnering model, the best partner is sought at an early stage, in order to reduce risk by co-ownership of the process and to allow seamless development and prevent knowledge loss at exit. The best partner is selected on the basis of the potential benefit for patients, thus the partner with the best scientific and product development concept per project is sought.
In situations where IP is shared, the participating EATRIS institutions will take part ownership thereof. The EATRIS ERIC itself does not participate in ownership of intellectual property. The activities of C&S are funded initially by contributions from members, but is expected to reach self-sustainability within 5 years by charging a small percentage overhead on projects, for services it renders.

Research project management
Development of novel medicinal products needs rigorous proof-of-concept and additional pharmacological-toxicological testing, be it in vitro or in vivo, in addition to defining a manufacturing process suitable to produce sufficient quantities of the product. This is governed by numerous scientific guidance documents as well as legal requirements having a strong impact on successful completion of even very early development steps from the laboratory stage onwards. In this respect e.g. choice of suitable raw and starting materials,

tests for absence of viral adventitious agents and proper validation of essential process steps are mandatory. Likewise, relevant preclinical models for primary and secondary pharmacology studies are crucial to ensure swift approval of early clinical trials. Respective rules and regulations are complex and often misinterpreted or even overlooked during the development of new active substances. Therefore, it is essential that any scientific project aiming at developing new diagnostic, prophylactic or therapeutic options depends on project management support to be provided by experts, also with experience in pharmaceutical development, regulatory affairs and quality assurance. Without such support it is nowadays unlikely that promising ideas and concepts will be developed to enter late stage research pipelines or development portfolios.
C&S is responsible for the Research Management (RM) Unit, whose responsibility it is to ensure that EATRIS projects are conducted with the above considerations in mind. The RM Unit is a typical support function and therefore the organisational structure is independent from operational product groups. EATRIS Centres provide input in the set-up of the RM-Unit and mandate their operational personnel to liaise with the group. Later, these persons act as centre-specific research managers ("Center-RMs"). In doing so, the RM-Unit fulfills its role as coordinating and project management function of the different projects in the different EATRIS centres. An important element of the RM unit's activities is the design of a suitable Development Plan for each project, encompassing:

1. Definition of the development goal (e.g. preclinical proof-of-principle, clinical first-in-man proof-of-concept, Market authorisation, license-out, etc.), possible "infliction points" (major milestones on the way), and the scope of the project.
2. Definition of appropriate development tasks. A development task may consist of a single study or a complex study program, depending on the nature and the status of the project.
3. Definition of timelines and resources needed to accomplish the defined development tasks
4. Definition of critical "Go/NoGo" decision points/milestones.
5. Identification and anticipation of potential risks that may occur during the project.

The development plan is written by the RM-Manager and is approved prior to start of the project. The respective project teams hold regular project meetings in order to review and update the development plan if required.

Financial sustainability
EATRIS is an innovative instrument established by national governments to support access to excellence in translational medicine, and to stimulate innovation in areas where the current model of financing is failing, such as rare diseases, unpatentable drugs, and others. At the same time the model allows the national government to extract the maximum benefit from financing their own research infrastructure and keeping their academic institutions to the top level of research, training, education and innovation. To ensure that this instrument is viable for the long term, EATRIS' objectives are to develop sustainable financial models for:

1. Investments in innovative translational research infrastructure in Europe - one of the overall objectives of building a state of the art consortium of translational research centres in Europe, is that national governments (co-)invest directly or indirectly in their own, national research infrastructure. By linking the national institutes together at EU level and providing capacity ('bricks, brains and cement'), EATRIS will provide a speedier process and innovative, more effective translational research pipeline to users, academia and industry. In the current financial and economic crises, national governments have limited capacity to invest in new infrastructure which will affect the level of innovation. Therefore we need to work together with the governments to analyse the situation, make scenario's of realistic, future investment potential, investment allocation and find alternative options and means to continuously upgrade innovation and capacity. Public private partnerships in Research Infrastructures (RI) investments will be explored as such an alternative option.

2. Co-financing of translational research projects in Europe - EATRIS provides research infrastructure to users. Co-founding can thus be obtained from academia, industry and 3rd parties like disease / patient group

specific and other life sciences funds. Though one of the key objectives of EATRIS is to provide services to make translational research speedier and more effective, projects will remain expensive and high risk. EATRIS will provide access but how will for instance excellent proposals by academic researchers be financed? And what is access worth if there are insufficient funding mechanisms? In the current set-up of EATRIS, cost for use of national infrastructure by external users will be partly absorbed by the EATRIS partners, by users and/or by national government support. However, co-financing mechanisms will still be needed to be able to co-fund future user projects. Project co-financing of translational research can be organized via EU wide (ERA) calls supported by governments, EU programs like FP7/8 and possibly external market based sources. In the framework of this proposal, we will develop organizational and financial models for EU wide calls, dedicated to translational research as well as perform a feasibility study to establish a dedicated, EATRIS project investment fund. If feasible, the fund will be established and start its operations within the project period.

3. The EATRIS Coordination & Support Office (C&S) - C&S is paid by contributions of the member countries and an extra contribution by the host country. The objective is to make C&S self-supporting by 2017. Every Product Group will develop a business plan including a forecast of their research, services and financial volume. Based on the outcome of the Product Groups financial projections, EATRIS will develop a suitable model to allow its coordination activities to become self-sustaining, perhaps via an overhead fee framework.

7. Embedding

EATRIS is one of several ESFRI initiatives in the life sciences domain. Given its unique position across a great deal of the biopharmaceutical development chain, there is significant potential for structural interaction with several other initiatives, in order to improve output of all initiatives, and to reduce wasteful overlap. The following initiatives will regularly interact with EATRIS:

BBMRI - Biobanking and Biomolecular Resources Research Infrastructure. This initiative holds a large repository of biomaterials, which will be a great source of added value for EATRIS projects as they seek to (re-)validate targets and establish stronger causal links.
ELIXIR and **BioMedBridges** - These initiatives will be instrumental in supporting the storage, access to, and inter-operability of the large amounts of data generated within and outside of EATRIS. This will improve dissemination of EATRIS data, and improve access for EATRIS researchers to other data.
EU-OPENSCREEN - European Infrastructure of Open Screening Platforms for Chemical Biology. This initiative is a rich source of candidate molecules and screening infrastructure for the small molecule product group, and as such will be a key partner to EATRIS activities in this area.
ECRIN - European infrastructure for clinical research infrastructures network. Given that EATRIS operates only up to phase IIa/b, the existence of the ECRIN network for the later clinical phases is a tremendous source of added value, as successful EATRIS projects will seek to further develop towards market authorization.
TRANSVAC – European Network of Vaccine Research and Development. This initiative offers complementary translational activities in the field of vaccine research, and thus will form an important partner for the vaccines product group. The differing types of available infrastructure between EATRIS and TRANSVAC will result in a highly comprehensive source of infrastructure in Europe in this area, in which a great deal of capacity is needed.
International embedding: Translational research is a global activity, and EATRIS seeks to engage the global community to improve its access to cutting edge knowledge, have top benchmarking platforms and to stimulate dialogue. Moreover, European institutions participating in EATRIS have the opportunity to share their experience and expertise with countries less experienced in the field. Such know-how sharing will be actively stimulated, and it is envisaged to establish exchange programmes with other, non-EU countries.

8. ERIC requirements

8.1 Necesssity

For the EU to become more competitive in the global arena, the functioning of the ERA relies on continuing innovation in technology and infrastructure, and the provision of unfettered access to such cutting edge facilities for the best researchers in Europe. EATRIS aims to fulfil exactly such a defragmenting and matching role. Via EATRIS, researchers are no longer limited to the translational infrastructure of their own institutions, or at the mercy of the slow and unpredictable process of ad hoc access to other institutions. Levelling out the playing field will increase speed, reduce uncertainty, and serve to improve both the quantity and quality of collaborative translational research projects in the ERA.

Moreover, the structural collaboration necessitated by participation in EATRIS serves to improve overall quality norms and foster better harmonisation of processes and common standards, allowing overall quality to improve and engender deeper integration of activities across the ERA.

8.2 Strengthening and structuring of the ERA

EATRIS has two primary objectives: firstly, EATRIS provides sufficient capacity of top quality expertise and infrastructure to serve a substantial part of European biomedical translational research demand; and secondly to foster a culture of co-operation between research infrastructures and scientific communities. These two objectives serve to improve the ERA significantly by virtue of the fact that no comparable initiative exists, and current third party access to such infrastructure is limited to ad hoc access to single institutions or small networks lacking critical mass and comprehensiveness of their offering. These ad hoc interactions are characterised by slow transaction speed, uncertain outcomes, lack of capacity and opaque access criteria. EATRIS is designed to remove all such stumbling blocks, organising effective collaboration and efficient access by top researchers to top infrastructure and expertise.

Besides the powerful multiplier effect of improved matching of services to actual need, the structural interaction of such top institutes will foster better best practice dissemination, and speed up innovation through cross-fertilisation, thereby accelerating the implementation and adoption of technological and process innovation across the ERA.

8.3 Effective Access

It is one of EATRIS' primary objectives to provide fast, efficient, transparent and equitable access to infrastructure. Users will be selected only on the basis of scientific merit, unmet medical need and translational potential. Furthermore, it is a strategic priority of EATRIS to support researchers in seeking funding for their projects, in order to prevent financial constraints from hindering excellent science.

Calls to submit proposals for access to EATRIS are communicated across the EU, and users encounter the same application process regardless of nationality, location and background. The selection of users is mandated to a board of (majority) independent international experts in the relevant field, working on the principles of fairness, transparency and impartiality. EATRIS also has in place a transparent, fair and efficient appeals process for applicants that have reason to believe that their submission was not handled properly.

8.4 Mobility

EATRIS is a truly international distributed infrastructure, and has a truly open access policy that encourages transnational access. Therefore it can be expected that mobility of knowledge and results will be very high. Furthermore, the focus on outreach, best practice dissemination and continuous innovation in all the product groups will further contribute to the mobility of knowledge.

Given that the infrastructure are advanced facilities and often require highly specialised, trained personnel to operate them, there is limited scope for physical mobility within EATRIS in the form of exchange. However, the active learning and education policy built around translational science will create a vibrant and

mobile community of translational experts, both existing and in training, that will spend time at various facilities and learn from their translational experts.

8.5 Dissemination

EATRIS has a very proactive policy towards dissemination, and where intellectual property arrangements allow, will actively distribute research results through publication in peer-reviewed journals and on the EATRIS website, participation in conferences and workshops, and the filtering through of knowledge gains into education curricula.

Furthermore, being translational in character and capable of handling both intellectual property-protected and open innovation projects, EATRIS has an active business development unit that disseminates the results of projects by partnering with the private sector and philanthropic organisations capable of bringing projects to a successful market entry. This is a key added value of EATRIS, and thus a great deal of effort will be spent to ensure that the contractual, intellectual property and regulatory elements of each project are optimal for future co-development, while development partners will be recruited at an early stage in the process to ensure optimal success chances of each project.